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Argonne National Laboratory

Advanced Photon Source

Quality Assurance Program Plan

February 2005

ADVANCED PHOTON SOURCE

Argonne National Laboratory

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Quality Assurance Program Plan

February 2005

Prepared and maintained by the Office of the Associate Laboratory Director for the Advanced Photon Source (APS)

The APS Document Control Center maintains the original document containing approval signatures for this plan.

This read-only version of this document, available on the APS intranet web system via the APS home page (www.aps.anl.gov), is the only controlled version of this document. All other copies (electronic or paper) must be reviewed against the controlled version.

Revision 2:

The APS QAPP has been revised to include the APS Software Quality Assurance document and Software Development Plan for Category I Software as Appendixes C and D, respectively, of this plan. Also, Criterion 6: Design has been updated to include software development.

Revision 3:

The APS QAPP has been revised to address the reorganization of the APS into the ASD, AOD and XFD Divisions, and changes to DOE O414.1B and the ANL QAPP as follows:
Changed DOE 414.1A Quality Assurance to 414.1B and 830.120 Quality Assurance to 830.122in the Introduction section
Replaced requirement for User QA Plans with reference to APS QA Plan
Replaced the term CAT personnel with Beamline personnel
Replaced the DOE quality requirements appearing in the double-lined rectangles with ANL QAPP requirements to all sections
Added The APS Organization Chart to section 1.3.1
Deleted all references to Senior Scientific Advisor
Added PU, OD, SAC and XOR to List of Abbreviations
Replaced the term CAT with Partner User
Replace references to the STAC with SAC
Changed all references to APS Mission to APS Vision and Goals
Added Quality Level for SSC's from section 1.2 to Appendix A, Table A-1
Added APS Project Management Process to section 1.1.1
Added the APS Policy on Design, Installation, and Maintenance of Radiation Safety Systems to sections 1.2, 5.1 and 6.1
Added ANL-E QEP 1.2 Corrective Actions Development and Tracking to section 3.1
Deleted DOE O 1324.2A Records Management from section 4.3
Added the APS Project Management Document to section 5.2
Added APS Design Review Procedure to section 6.1
Added ANL-E QEP 3.4 Conducting Management Walk-Throughs to section 5.6
Added the APS Design Review procedure to section 6.0
Added ANL-E Procedure 2.2 Suspect Counterfeit Items to sections 7.1 and 8.1
Added ANL-E QEP 2.1 Nonconformance Process to section 7.2 and 8.1
Added ANL-E QEP 3.1 Management Assessment to section 9.1
Added ANL-E QEP 3.2 Independent Assessment to section 10.1
Added Component Classification to Appendix A, Table A-1
Added Complexity probability to Appendix A Table A-2
Changed Qualitative Probability values in Table A-2 to Likely, Neither likely or unlikely, and Unlikely

Revision 3 continued:
Added APS Policy on Design, Maintenance, and Operations of Radiation Systems to Appendix A Table A-3
Added APS Design Review Procedure Appendix A Table A-3
Updated Table C-1 APS Software Categories
Added a fourth column to Appendix A Table A-3 to better implement applicable policies, procedures and forms
Updated Appendix C Table C-1 to comply with DOE414.1B and APS R&I Matrix

Argonne National Laboratory

Advanced Photon Source

Quality Assurance Program Plan

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LIST OF ABBREVIATIONS

ACIS	Access Control and Interlock System
ADD	Associate Division Director
ALD	Associate Laboratory Director
ANL	Argonne National Laboratory
AOD	APS Operations Division
APS	Advanced Photon Source
ASD	Accelerator Systems Division
COATS	Corrective Action Tracking System
DCC	Document Control Center
DOE	U.S. Department of Energy
ESH	Environment, Safety, and Health
GERT	General Employment Radiation Training
ISM	Integrated Safety Management
JHQ	Job Hazard Questionnaire
LOI	Letter of Intent
MOU	Memorandum of Understanding
NEPA	National Environmental Policy Act
NTS	National Tracking System
OJT	On-the-Job Training
OD	Operations Directorate
ORPS	Occurrence Reporting and Processing System
PAAA	Price-Anderson Amendments Act
PD	Position Description
PEB	Program Evaluation Board
PI	Principal Investigator
PU	Partner User
QA	Quality Assurance
QAP	Quality Assurance Plan
QAPP	Quality Assurance Program Plan
QAR	Quality Assurance Representative
SAC	Scientific Advisory Committee
SAD	Safety Assessment Document
SMART	Safety Management Records Tool
SSC	Structures, Systems, and Components
USI	Unreviewed Safety Issues
XFD	Experimental Facilities Division
XOR/MT	XOR Management Team

ARGONNE NATIONAL LABORATORY

ADVANCED PHOTON SOURCE

QUALITY ASSURANCE PROGRAM PLAN

INTRODUCTION

GENERAL

This Quality Assurance Program Plan document is a guide for how work is to be conducted at the Advanced Photon Source (APS). Quality achievement is a continuing responsibility of line organizations at all levels of APS operations. Each individual at the APS is responsible for achieving quality in his/her own work. The object of this document is to define the management controls within the APS by which its quality assurance (QA) program will meet ANL and DOE goals.

This APS Quality Assurance Plan (QAP) is structured according to and satisfies the criteria specified in the *ANL Quality Assurance Program Plan* (QAPP) and DOE Order 414.1B, *Quality Assurance,* and therefore meets the requirements as stated in the ANL Policy on *Quality Assurance* given in the ANL Policy Manual. Further, in accordance with the guidance given in DOE G 414.1-2, *Quality Assurance Management System Guide* and in 10 CFR 830.122 *Quality Assurance Requirements* the principles and core functions described in DOE P 450.4 *Safety Management System Policy* are embodied in this QAP.

The APS has no plans to achieve third party certification of its QAP, but uses national or international standards, such as ASME NQA-1, ISO-9001 and ANSI/ASQ Z1.13 when applicable, when required by ANL Policy, or when contractual or regulatory organizations require. The APS will inform EQO of any plans to obtain such certifications.

Two definitions of importance for this document are:

> Quality: The condition achieved when an item or process meets or exceeds the user's requirements and expectations.
>
> Quality Assurance: All those actions that provide confidence that quality is achieved.

PURPOSE AND SCOPE

The Advanced Photon Source is a world-class synchrotron radiation facility that provides a stable source of X-rays to collaborative teams of researchers. Providing the X-rays requires efficient machine operations. Quality assurance at the APS refers to those actions that provide confidence that the items, services, or processes provided by APS meet or exceed the user's requirements and expectations and that the actions are performed safely. This plan sets forth the methods, controls, and processes and defines the responsibilities and lines of communication for assuring that the desired quality is achieved at the APS.

Specific requirements of this QAP are to be applied in all tasks at APS using a graded approach. The stringency with which the requirements of this QAP are applied will be commensurate with the risk of occurrence of undesirable outcomes with respect to health and safety, the environment, property, resources, as well as the APS vision and goals. APS Management ensures that necessary and appropriate resources and capabilities are provided to maintain compliance with the requirements of this document. Any significant variances to the requirements in this QAP are documented and established for a specific time period not to exceed one year. Variances to this plan are approved by the APS Associate Laboratory Director (ALD).

All personnel, including contractors and students that perform work at the APS, are responsible for carrying out their assignments in accordance with the requirements established in this QAP. More stringent quality assurance requirements may be imposed for specific activities. Expectations for quality assurance specified by sponsors are incorporated into the research program documentation. In such cases, the research program documentation will reference this QAP and specifically note any exceptions being made to the requirements.

QUALITY ASSURANCE PROGRAM BASIS

The APS QA Program is based on the following fundamental principles:

1) Achievement of quality is a line responsibility wherein each performer and supervisor is accountable for the quality of work assigned.

2) The degree of application of quality assurance criteria is dependent on the magnitude of risk associated with the potential failure of the structure, system, or component involved. This is accomplished through the use of “graded” quality assurance measures.

3) A no-fault attitude is fostered by management to encourage the identification of nonconformances so that processes can be improved to prevent recurrence.

SECTION A – MANAGEMENT

1.0 PROGRAM

Each organization must develop a QAP specific for its work that addresses program requirements for each of the ten quality assurance criteria given in the QA Policy. The QAP must describe the following: [1]

Organizational structure.

Functional authorities, responsibilities and interfaces describing as a minimum: Division Director. QAR. Supervisors. Employees. Committees, as appropriate.

Management processes, including planning, scheduling, and resource allocation.

This QAP establishes the requirements for the quality assurance program at the APS. This section describes the organizational structure at the APS and the functional responsibilities, levels of authority, and interfaces for the different levels in the organization. The management processes used at APS for planning, scheduling, and resource considerations are also discussed in this section.

1.1 Overview of APS

1.1.1 APS Vision and Goals

The Advanced Photon Source vision and goals are published on the APS home page, and are achieved through the coordination of efforts in the APS Operations Division (AOD), the Accelerator Systems Division (ASD), and the Experimental Facilities Division (XFD), and within the constraints of its available resources and in a manner that promotes safety and health, and environmental preservation. The APS complies with appropriate federal and state laws, with U.S. Department of Energy (DOE) orders and policies, with Argonne National Laboratory policies and procedures, and with the University of Chicago contract governing the operation of Argonne National Laboratory (ANL).

1.1.2 Identifying Vision and Goals

The APS vision and goals are based on Office of Basic Energy Sciences Office of Science expectations, and commitments to its sponsors and customers. Specific long-term goals and short-term objectives are established at the division level and reviewed by APS management each year to assure that the work supports the overall APS visions and goals. As appropriate, the

[1] The requirements identified within the box are those defined in the ANL QAPP, dated September 30, 2004.

goals are prioritized to ensure that resources are allocated correctly. Requirements to meet the organizational goals are also established at the division level; APS management reviews the requirements and assures that the appropriate resources are provided to the divisions.

Individuals working at the APS are informed periodically about objectives, goals, and requirements through APS User meetings, APS All Hands meetings, and division meetings and/or written communication. Goals are also published on the APS and division web pages. Individual goals, objectives, and requirements are communicated to workers by their immediate supervisors. APS management encourages input and feedback from all workers to help clarify overall goals and missions of their divisions and to improve safe work practices.

1.1.3 ESH Hazards

Work at APS takes place in various environments, including offices, laboratories, construction sites, and industrial-like settings. Hazards at APS include ionizing and non-ionizing radiation exposure, chemical hazards, high voltage and current, high magnetic fields, mechanical actuators, and pressurized gas and water systems. Exposure to these hazards is minimized by a combination of engineered controls, administrative systems, and training. These hazards have been evaluated in detail during the development of the APS Safety Assessment Document (SAD) and the precommissioning reviews. Subsequently, the APS conducts annual self-assessments designed to assess and evaluate potential hazards identified at the APS.

1.2 Quality Assurance Levels (Grading)

The APS QA program is organized such that structures, systems, and components (SSCs) are classified into one of three QA levels (A, B, or C). Each level is characterized by the level of confidence needed to assure that requisite quality is achieved.

Quality Assurance Level A (High QA Risk) applies to SSCs that are necessary to keep visitor and worker radiation exposure levels below the limits specified by safety analysis, and to those SSCs specifically identified as Level A by facility or division management.

Quality Assurance Level B (Moderate QA Risk) applies to SSCs that are not Quality Level A, but whose preventative or mitigative function is a major contributor to defense in depth (i.e., prevention of uncontrolled material releases) and/or worker safety as determined from hazards analysis. Level B also applies to SSCs that are required for programmatic data generation or reduction or that are identified by facility or division management as important to facility safety or mission objectives.

Quality Assurance Level C (Low QA Risk) applies to SSCs that are not critical to mission objectives and whose failure would not result in significant risk to worker safety or loss or impairment of data generation.

Because it is recognized that a uniform method of applying the requirements of this QAP across all items and activities at APS does not necessarily add value or reduce risk, the APS defines requirements with a graded approach. The APS graded approach is based on the expected risk to personnel, to the APS visions and goals, or to the environment. Issues that are critical to the current or future success of APS or that have the potential to cause grave danger receive significantly more attention and support than those issues deemed to be trivial. The level of compliance established by APS line management is based on input from the ESH/QA Program Manager, the Quality Assurance Representatives (QARs), and regulators, as appropriate.

The line managers assess safety and operations risk levels associated with activities for which they are responsible using the grading matrix found in Appendix A of this document, in the APS Design Review Procedure x.3.1.1, and in the APS Policy on Design, Installation, and Maintenance of Radiation Safety Systems document #1-01304 found on the APS web pages.

Line managers can use discretion in applying these requirements, but should strive for consistency. Not all assessments are documented where line management establishes that there is not a need to do so.

1.3 APS Organization

1.3.1 Overview of Structure

The APS organization is managed by an Associate Laboratory Director (ALD). The APS is divided into an ALD staff and three divisions (APS Operations, Accelerator Systems, Experimental Facilities). Each division is further divided into subunits headed by a Group Leader/Manager; the divisions may have one or more layers of management between the Director and the groups. The APS Organization Chart is available on the APS home page or by accessing the following url: www.aps.anl.gov/About/Organization/index.html.

The Group Leaders generally supervise the work and are the main interfaces for those managing, performing and assessing the adequacy of work. Each division is supported by an ESH Coordinator, a QAR, and an administrative staff. The roles and responsibilities for each of the functionaries at APS are discussed below.

Several advisory committees and oversight organizations also support the APS and its divisions. These independent organizations provide input in programmatic, quality, and safety areas. These organizations include the University of Chicago review committees, the ANL Accelerator Safety Review Committee, the APS Scientific Advisory Committee, and the APS safety committees. A listing of APS committees can be viewed on the APS webpage or by openging the following url: http://www.aps.anl.gov/About/Committees/index.html .

1.3.2 Authority and Responsibilities

An overview of the authorities and responsibilities for each of the main functional positions at the APS is given below. Specific responsibilities of the main positions are given in Appendix B.

Associate Laboratory Director – The Associate Laboratory Director for the Advanced Photon Source (ALD-APS) provides overall scientific and managerial leadership for the APS organization and is responsible for assembling the scientific and management team that operates the APS. The ALD has overall responsibility for the quality of the work performed at APS and for the QA program.

Deputy Associate Laboratory Director – The Deputy ALD serves as the ALD-APS and assumes all authorities and responsibilities in the absence of the ALD. The Deputy ALD is specifically responsible for overseeing the operation of the APS, for the conduct of the research performed by the APS, and for ensuring that the needs of the user community are satisfied.

ALD ESH/QA Program Manager - The ALD ESH/QA Program Manager reports to the ALD-APS and is the main point-of-contact for both environment, safety, and health (ESH) (including NEPA) and QA issues at the APS. He coordinates ESH and QA policy at the APS. The ALD ESH/QA Program Manager is responsible for ensuring that this Plan is applied in a consistent manner across the APS.

Division Directors – Division Directors are responsible for establishing and maintaining the organizational structure, functional responsibilities, and levels of authority necessary to support their respective division goals and objectives. Further, each Division Director establishes appropriate performance measures by which to assess the work.

Associate Division Directors –Associate Division Directors report to their respective Division Directors on the status of their groups and inform their technical groups of division policy and goals. In the absence of the Division Director, an Associate Division Director (ADD) (or in the absence of an ADD, another designee) is assigned to act on behalf of the Division Director and assume the authority and responsibilities of the Division Director.

Group Leaders/Managers - Group Leaders/Managers are responsible for the management and operation of their respective operations within the constraints of their individual budget and schedule requirements. Group Leaders/Managers are also responsible for assigning line management responsibilities to their subordinates.

Quality Assurance Representative (QAR) – A QAR is assigned to each division at APS and reports directly to the Division Director. Each QAR is responsible for ensuring that this QAP is implemented and applied in a consistent manner within the division. Each QAR monitors ANL, APS, and divisional QA programs and policies to ensure they are appropriate and consistent. Each QAR reviews this plan annually and provides input for its revision.

ESH Coordinator – An ESH Coordinator is assigned to each APS division. Each coordinator is responsible for implementing and coordinating ESH-related policies at the division level and for ensuring that such policies are applied consistently within the division. Each coordinator monitors ANL, APS, and divisional ESH programs and policies to ensure they are appropriate and consistent. Each coordinator ensures that the requirements of this QAP are applied in developing and implementing ESH policies and issues.

Building Manager – One building manager is assigned for the APS complex of buildings in the 400 Area, which does not include the Utility Building or the Guest House. Separate managers are responsible for the Utility Building (Bldg. 450) and the Guest House (Bldg. 460). The building manager is the main point of contact for all items/services related to the building structure, operation, and utilities under normal conditions. The building manager oversees work, maintenance, and facility services. The building manager reports to the AOD Director.

Floor Coordinators – Floor coordinators serve as the primary interface between the users and the APS. The floor coordinators are the points of contact for items and services provided to the users and provide APS oversight of the user activities. The floor coordinators report through a Group Leader to the AOD Director.

Area Emergency Supervisors – Area emergency supervisors are identified for each building and serve as a point of contact in an emergency situation. They supervise evacuations and provide initial direction for emergency response. Other emergency management roles are specified in the ANL-E Emergency Management Plan.

Personnel – All individuals performing work or conducting experiments are responsible for conducting daily activities in accordance with the principles and requirements of this QAP. Each individual is responsible for the quality of his/her work and for being attentive to the opportunities for continuous quality improvement. All personnel are responsible for stopping any activity that poses imminent danger to any individual, the APS vision and goals, their Division's mission, or the environment, and notifying management. Workers inform their immediate supervisor of any conditions that are noncompliant with APS or ANL policies, procedures, and instructions or any conditions that are unsafe.

2.0 PERSONNEL TRAINING AND QUALIFICATION

Laboratory organizations must: [2]

Ensure that personnel possess the experience, knowledge, skills, and abilities that are necessary to discharge their responsibilities.

Use appropriate administrative controls, such as assigning an escort or providing systematic on-the-job-training, if personnel do not have education and training commensurate with the requirements of their assignments.

2.1 Requirements

2.1.1 General

Personnel at all organizational levels have the training and qualifications (education, experience, and skills) to be capable of performing assigned tasks. This includes personnel involved in managing, supervising, designing, planning, purchasing, operating, training, maintaining, fabricating, verifying, and assessing. Training is subject to ongoing review to determine its effectiveness and is upgraded for improvement, as necessary.

Training requirements for personnel at APS consist of general training, site-specific training, and job-specific training, and are established for each worker. Training requirements are based on an assessment of the job requirements and specific hazards that each worker may face. Site-specific training is related to the work location and includes a walk-through by the worker's immediate supervisor to ensure that each worker is familiar with evacuation routes and proper emergency responses. Job-specific training requirements are determined by Group Leaders/Managers and administered to the worker locally.

Records of training are maintained for each worker at the division level using the ANL Training Management System (TMS) where possible.

2.1.2 New Employees

All new APS employees complete a New Employee Orientation Checklist, which is specific for each division. One purpose of the checklist is to document that all employees have completed their Job Hazards Questionnaire and received safety training consistent with their jobs and the hazards they may face. The checklist also assures that the employee is introduced to ESH and QA personnel in their division office. The completed checklist is signed by the employee's immediate supervisor and is maintained in the employee's training file, which is kept in the Division office.

[2] The requirements identified within the box are those defined in the ANL QAPP, dated September 30, 2004.

2.1.3 General Training

The first component of the APS training program is general training, which is typically subject-based, classroom training geared toward job proficiency and safety/quality-significant issues. However, it may also include management training and continuing education through courses and seminars. To determine the requirements for the type of general training, the following steps are taken. Position descriptions (PDs) are developed and maintained for each nonunion employee in APS in accordance with *ANL Human Resources Guidelines for Completing the Position Description.* The PDs reflect the hazards that each employee may encounter during the normal conduct of his/her job and include the minimum knowledge, skills, and experience required to do the job effectively. Each staff member's PD is reviewed annually as part of the performance evaluation process to assure that it is maintained current.

For union employees, PDs are written for each grade, rather than for each individual. The PDs contain assignments for each grade. For union employees, performance reviews are completed on an ad hoc basis.

A Job Hazard Questionnaire (JHQ) is completed for every employee and for any significant change in job assignment or in the PD. The JHQ is signed by the employee's immediate supervisor, the employee, and the appropriate ESH Coordinator, and submitted to the TMS Representative in the appropriate division or in the ALD office.

A training profile is generated for each JHQ that lists the general safety training requirements for the employee's job assignment. The employee's immediate supervisor reviews the training profile to ensure that the identified course requirements address the job hazards faced by the employee. The TMS Representative may modify the training profile, as directed by the supervisor. The supervisor signs a copy of the training profile to indicate approval of the profile and a copy is maintained in the division's training file for the employee. The supervisor and employee agree to a training schedule to assure that required courses are completed in a timely manner.

2.1.4 Work at Non-ANL Facilities

In general, the determination and provision of facility specific training is the responsibility of the host facility. When reciprocity for ESH training is extended by non-ANL facilities, the training profile of the APS employee may be sent to the host facility upon request.

2.1.5 Site-Specific Training

In addition to ANL general safety training, ANL employees are also provided with site-specific training related to their specific work location. Each employee's immediate supervisor defines the need for site-specific training. For example, all employees complete Building Safety Training for each building in which they work more than 20% of their time.

2.1.6 Job-Specific Training

Job-specific training may also be required for APS employees, to address the specific tasks they have been assigned. Job-specific training may consist of on-the-job training (OJT), "classroom" training designed for and provided by APS personnel, and continual training provided by casual forums such as group meetings. All job assignments generally have some level of job-specific training. The training for higher risk jobs is formally documented and may require very specific and detailed certifications (e.g., Accelerator Operator).

2.1.7 Training Records

A record of training is maintained for every APS employee at the division level. The record includes a copy of the employee's JHQ, training profile, and copies of other pertinent memos, certificates, and documents. The records of all employees hired after the effective date of this QA Plan include a copy of the completed New Employee Orientation Checklist. Each division's TMS Representative maintains personnel training records. For APS-based training, each employee is to inform his or her TMS Representative of the training that has been completed and provide appropriate documentation.

Each employee is expected to ensure that his or her respective training is current. Employees, their Group Leader/Manager, the ESH Coordinator, the Division Director, and the TMS Representative may access the employee's online TMS record and the employee's training file. Discrepancies are reported to the TMS Representative for corrective action. The Division Director and Group Leader/Manager review the training status of their employees monthly.

2.1.8 Review of Qualifications and Training

An assessment of an employee's training profile is conducted annually with the employee as part of the Performance Review process, or in the case of technicians, at some appropriate time. Employees are expected to inform their immediate supervisor of any special training needed to permit them to accomplish their assignment. Employees are encouraged to report evaluation of training received and suggestions for improvement.

2.2 Training for Students, Temporary Employees, and Contractors

Depending on the job and duration of the assignment, the training requirements may be as comprehensive as those outlined above for APS employees. For all students, temporary employees, and contractors performing work for APS, there is an APS point of contact. The point of contact determines the training requirements and ensures that the appropriate training has been completed or is provided.

Students and temporary employees are considered APS employees and follow the process in Section 2.1. A training record is established for each student and temporary employee.
For contractors, APS follows the guidelines discussed in the ANL-E ESH Manual, Chapter 17-1. In addition to the ANL-wide requirements, contractors receive a building orientation from the

building manager or other appropriate personnel for the building in which they will work. Other specific training requirements are stipulated in the contract and completed before the contractor starts work.

2.3 Training for Users

The APS User Office provides users with General Employee Radiation Training (GERT) and facility orientation classes that address building safety and emergency plan information. Sector-specific training for APS users is the responsibility of the Partner User management. As necessary, the APS makes arrangements for users to attend courses offered by ANL or APS personnel. The Partner User management maintains user training records. In addition, the AOD TMS Representative maintains TMS records of ANL courses taken by users.

2.4 Training for Support Personnel

Support personnel are those ANL employees who are not administered by APS management but who work in APS buildings (e.g., ECT installation and electronics support, PFS maintenance personnel). Training for support personnel is the responsibility of their immediate supervisor. APS building safety training is available to support personnel on the Web.

2.5 Training for Visitors

Visitors are those individuals who come to the APS on a short-term basis for tours, conferences, meetings, or other similar events. If a visitor remains in Building 401 and the Viewing Gallery, no APS-specific training is required. The visitor's host is expected to guide the visitor to safety if an emergency should occur during the visit.

Visitors to beamline facilities are the responsibility of the beamline personnel and are escorted, or trained in accordance with Section 2.3.

3.0 QUALITY IMPROVEMENT

Laboratory organizations must: [3]

Establish and implement processes to detect and prevent quality problems.

Identify, control, and appropriately evaluate and disposition items, services, and processes that do not meet established requirements. Evaluation and disposition must include identifying the causes of problems and working to prevent or minimize the probability of recurrence.

Review item characteristics, process implementation, and other related information and analyze to promote improvement.

All personnel who work at the APS strive for high quality and continual improvement in their work at the APS. Personnel at all levels are involved in goal setting and methods for quality improvement. Potential problem areas or improvement opportunities (collectively referred to as issues) are identified, communicated to management, and evaluated, corrected, and improved. Issues may be problems, noncompliances or nonconformances, and opportunities for improvement related to any item, service, or process. Issues may be identified in both facility operations and research and development (i.e., data quality).

3.1 Identification and Communication to Management

Issues are identified and communicated through formal or informal means by individual employees, APS management, and by outside suppliers, subcontractors, auditors, and assessors. Personnel identify and report issues to their immediate supervisor; issues may also be reported through one of the communication systems in place at APS.

Formal systems available to employees for reporting issues to management include the ANL IMPACT system, the APS suggestion envelopes, the APS electronic Improvement Suggestion box found on the APS home page, and the APS Safety Suggestion & Concern (anonymous e-mail) found on the APS Safety Web page. The APS Corrective Action Tracking System (COATS) enables APS employees to enter and track the corrective measures taken to address their ESH and QA observations. The COATS system also allows APS employees to comply with section 2.1 of ANL Quality Assurance Plan, by providing a corrective action tracking system. Issues of concern may also be raised and discussed during group meetings, during performance evaluations, or during informal meetings. Other methods that may be used to identify issues include the following:

[3] The requirements identified within the box are those defined in the ANL QAPP, dated Septermber 30, 2004.

- Job safety analysis
- Work request permits
- Radiation work permits
- Machine protection system validation procedures
- Access Control and Interlock System validation procedures
- Employee behavior observation program
- Acceptance Criteria Listings (ANL-266)
- Reports of Nonconformance (ANL-267)
- Vendor feedback
- Safety reviews
- Price Anderson Amendment reviews
- Technical system design reviews
- Group-level procedure walk-throughs
- Periodic procedure reviews

APS employs DOE systems (e.g., Occurrence Reporting and Processing System (ORPS) and National Tracking System (NTS) for deficiency or safety issue identification and tracking when appropriate. For reporting on the DOE systems, the APS follows the guidelines established in the ANL-E ESH Manual.

DOE-complex-wide issues also provide a source of information for opportunities for improvement, suchs as is disseminated through Department of Energy (DOE)/National Nuclear Security Agency (NNSA) Society for Effective Lessons Learned Sharing (SELLS) Learned (SELLS) and their listservers. APS ESH Coordinators review ORPS reports periodically to determine the applicability of experiences at other DOE facilities to the APS. Reporting information to the DOE systems is the responsibility of the ALD ESH/QA Program Manager with input from the ESH Coordinators and others, as appropriate.

Issues may be identified during Management Assessments (see Section 9), Independent Assessments (see Section 10), safety inspections, or informal “walk-throughs.”
Issues and opportunities for improvement may also be identified as part of the scientific reviews completed for each division. The University of Chicago conducts biennial reviews of the APS scientific and technical accomplishments to ensure its mission is appropriate to ANL goals and objectives.

3.2 Communication of Management Issues

Communication of management issues to division personnel takes place at APS and Division meetings, during performance evaluations, and in other formal or informal settings. Management at APS also uses memos, e-mails, electronic broadcast system, bulletins, and APS-wide meetings. ANL management may communicate issues with a broader scope through similar methods.

3.3 Disposition (Evaluation, Correction, Improvement)

Issues involving items, services, and processes received at the APS are addressed in accordance with Section 8.0 of this plan. Each issue is evaluated for its potential impact and the level at which corrective action will be effected. Line managers determine if an issue should be evaluated and corrected at their level and/or whether other levels of management should be involved. Issues that require a decision by APS management are brought to their attention. Line managers consider each issue to determine if it contains lessons for others. This information is then disseminated to the other APS divisions and/or to outside suppliers and contractors as appropriate.

Evaluation of an issue and the appropriate course of corrective action may be done informally or by formal, accepted methods, such as fault-tree analysis. The responsible line manager determines the appropriate evaluation method based on the severity and complexity of the issue.

3.4 Identification and Resolution of Issues

The resolution of issues of concern may be addressed directly with the individual concerned or may take a more formal approach that includes documented corrective action(s). In either event, APS management strives to provide timely solutions to issues of concern and to prevent their recurrence, and promote improvement. All actions are evaluated for their ESH implications and potential effects on quality of other items, systems, and processes.

The resolution of significant issues is documented and tracked. Depending on the issue, documentation may be through COATS, memo/e-mail, ORPS/NTS, CAIRS, or through the Unreviewed Safety Issue (USI) process if the issue affects the SAD/Accelerator Safety Envelope (ASE). The person completing the evaluation determines the level of documentation.

3.5 Ensuring Improvement

Line management periodically evaluates operational practices to determine whether different or modified practices would more effectively address management goals. APS line management regularly evaluates the resolution of issues of concern. If a resolution is found to be deficient, the issue is immediately reevaluated to determine a more appropriate course of action.

4.0 DOCUMENTS AND RECORDS

Laboratory organizations must: [4]

Document policies, procedures, other requirements, and designs, and make that information available to employees who need it to achieve quality.

Review, approve, and maintain up-to-date the above documentation.

Specify, prepare, review, and approve records that contribute to or demonstrate quality.

Retain quality-related records for the period of time specified by DOE records retention schedules.

The guidelines provided in this section defines the process for the generation and control of documents and records. Documents and records may be in either hard-copy (paper) or electronic (Web-based or computer-based) form. The APS also has begun to implement an electronic content management system (ICMS) to assist in the management of documents and records.

Documents are written and/or graphical information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.
Records are documentary materials that meet both of the following conditions:

(1) They are made or received by an agency of the United States under Federal law or in connection with the transaction of agency business, and

(2) They are preserved or are appropriated for preservation as evidence of the agency organization and activities or because of the value of the information they contain.

Records are signed and dated by the preparer, reviewer(s), and approver.

4.1 Documents

Processes and procedures used for operations and programmatic activities at the APS are clearly documented. When applicable, these documents include appropriate quantitative or qualitative acceptance criteria or performance indicators for determining that the prescribed activity has been accomplished satisfactorily. Other documents include design calculations and record of checks, design deviations, final inspection reports, calibration documents, construction permits, construction project data sheets, cleaning procedures and results, etc.

Documents are prepared by those individuals responsible for the subject areas discussed in the documents. Review and approval of documents are conducted at a level commensurate with the risk involved and/or the authority necessary to establish the requirement.

[4] The requirements identified within the box are those defined in the ANL QAPP, dated September 30, 2004.

Procedures are prepared, reviewed, approved, and revised in accordance with the following guidelines and other division guidelines, as appropriate. If applicable, the content of the procedure should include the following items:

- Purpose/scope
- List of equipment/tools necessary for the task. Manufacturers, model numbers, and serial numbers are specified when appropriate.
- Materials necessary for the task. Material specifications (composition, properties, etc.) may be stated and used on purchase documentation when materials are ordered.
- Related documents (drawings, equipment manuals, etc.) that should be available at the start of the task.
- Hazards related to the task and safety precautions, warnings, and controls necessary to complete the task.
- Step-by-step protocol needed to accomplish a certain task. Hold points (for quality verification, safety, or other reasons) and visual aids should be included when appropriate.

Reviewers of procedures include an individual independent of the originator and familiar with the subject area. The ESH Coordinator and the QAR for the appropriate division also review the procedure if deemed necessary by line management. Review by the latter two functionaries ensures that ESH and quality issues have been appropriately addressed. The line managers responsible for the work approve the procedure.

4.2 Document Control

Document control is a method of ensuring that the current and correct versions of a document are available and identified as such. Further, document control is a practical mechanism for ensuring that each controlled copy is maintained and up-to-date.

All documents considered critical to the successful or safe operation of the APS are controlled documents. Other documents may be controlled at the discretion of the approval authority. Controlled documents contain the following information:

- Names of the originator, reviewer(s), and approver(s)
- Organization responsible for periodic review and revision or elimination of document
- Date of creation and required review date
- Document number. For drawings (and related documents) and manuals, the Work Breakdown Structure (WBS) number is used as the document number. For

procedures and other documents, the numbering system is determined at the division level.

The APS Document Control Center (DCC) is the centralized repository for all manuals, technical specifications, statements of work, drawings, and other documents pertaining to the configuration of the APS or installed systems contained within the APS Experiment Hall shield wall (ratchet wall). The APS DCC Manager controls the following documents, their revision, and dissemination:

- Manuals, including this QA Program
- Project/Task QA plans
- Design review and verification documents
- Drawings
- Technical specifications and statements of work
- Corrective action requests
- Conceptual design report
- Certificates of compliance and conformance
- Audit reports
- Acceptance test procedures
- Equipment inspection acceptance documentation

The originating group controls APS-generated software and documentation. Review, revision, and dissemination of procedures and other documents is completed at the division level.

A secure master file of the original controlled copy of all ANL manuals related to the operation of APS (e.g., the ANL-E ESH Manual) is available in the DCC. Access and security precautions have been established to ensure that the master file is controlled and kept current. Master files are not released from the DCC. Reproductions of ANL Manuals are available on the Argonne Website (http:// http://www.aim.anl.gov/manuals/), in the Bldg. 401 library, or in the ALD or division offices.

4.3 Records

The requirement for generating a record is defined in originating documents (e.g., a procedure that requires data to be taken, or a process that specifies that a logbook shall be maintained). Documents that establish the requirement for records also define the format, approval, and maintenance of the records.

The criteria for record requirements follow ANL Records Management Policies and DOE Orders. The generator, or responsible line manager, also maintains a copy of the record.

The ALD ESH/QA Program Manager maintains records related to the overall compliance of the

APS with the requirements of this QAP, such as independent assessment reports and summaries of management assessment reports completed at the division level. The ALD ESH/QA Program Manager maintains a file of all ESH/QA records transmitted to ANL management or DOE, such as Unreviewed Safety Issues.

For each division, the Office of the Division Director maintains records such as:

- Planning and scheduling records
- Experimental proposals
- Interim experimental reports
- Publications file
- Progress (assessment) reports
- Training files
- Division property records
- Purchase orders
- Memoranda and reports generated by the Division Director or his staff
- User agreements

The ALD/AOD offices maintain records pertaining to the development and operation of each of the BEAMLINEs, including: Letters of Intent (LOI)

- Proposals
- Design reports (preliminary and final)
- Approved management plans
- Approved safety plans
- Beamline Review Committee reports
- Beamline Commissioning Readiness Review Team reports
- Memoranda of Understanding (MOU)
- Scientific Advisory Committee reviews
- Approved independent investigator plans

For each technical group or section, the Group Leader/Manager maintains records such as:

- Budgets for the group
- Operating log books
- Equipment Parameter Sheets
- Radiation safety system interlock checkouts
- Accelerator tunnel entry records
- Accelerator radiation distribution maps
- Accelerator status reports

- Equipment reliability comparisons
- Accelerator downtime studies
- Worker qualifications forms
- Operating safety requirements test data
- Service requests
- Quality assurance records
- Experiment safety approval forms
- As-executed check-off procedure copies of ACIS validation
- Documents specifying requirements for day-to-day operations
- Documents for modifying the facilities, e.g., design requirements, design calculations, and accident analyses

Principal Investigators (PIs)/Staff maintain records related to their projects. Records maintained by PIs/Staff may include:

- Laboratory notebooks (related to inventions)
- Computer software and data acquisition media
- Progress reports
- Design requirements including applicable codes and standards
- Design review reports
- Design verifications and amendments
- Design deviations
- Safety review documents
- System descriptions
- Procurement packages
- Project management plans, schedule and cost summaries
- Process procedures
- Inspection or test plans
- Project QA plans, if applicable
- Nonconformance, corrective action, QA audits, and occurrence reports

When a project ends or a PI leaves, all records are reviewed and archived by the DCC Manager in accordance with the ANL Records Management Policy.

SECTION B - PERFORMANCE

5.0 WORK PROCESSES

Laboratory organizations must: [5]

Perform work consistent with established technical standards, administrative controls, and other hazard controls (appropriate to the task) using approved instructions, procedures, or other appropriate means.

Identify and control items needed to perform work to ensure their proper use.

Maintain items needed to perform work to prevent their damage, loss, or deterioration.

Calibrate and maintain equipment used for process monitoring or data collection of moderate- or high-risk activities.

The work processes established at the APS are defined to satisfy the intent of the above criteria using a risk-based graded approach. The APS work philosophy is to achieve its vision and goals using the available resources most effectively and assure that ESH considerations are addressed.

5.1 Overview

The APS vision and goals is translated into day-to-day activities through established lines of management. Responsibility for controlling and assuring both quality and safety is integrated into the work process and assignment of work. The performance of work at the APS is consistent with the five core functions of Integrated Safety Management (ISM). All work has a defined scope; it is planned; the hazards and potential consequences of the activity are identified and analyzed; appropriate controls are defined and implemented; the work activity is performed within the defined limits; and the completion, results, and feedback are reported to the assignor of the activity. The formality with which each step is performed is based on a graded approach consistent with the guidance provided in the grading matrix found in Appendix A of this document, in the APS Design Review Procedure x.3.1.1, and in the APS Policy on Design, Installation, and Maintenance of Radiation Safety Systems 1-01304.

5.2 Work Scope/Planning

Work performed at the APS is based on APS vision and goals and available funding. APS management translates the APS vision and goals into division projects and programs during its annual budget cycle, and as defined in the APS Project Management document found at www.aps.anl.gov/ Internal/ Project Proposal/index.html.

[5] The requirements identified within the boxes are those defined in the ANL QAPP, dated September 30, 2004.

Group Leaders/Managers further define tasks and activities in formal work plans, memorandums, or as part of meeting minutes. Tasks and activities may also be listed in a work schedule or assignment list and assigned during a group meeting or defined as part of a formal procedure. The level of planning for each work activity depends on the hazards and risks associated with each task.

APS management will prioritize work to ensure that sufficient resources are available for divisions to carry out their missions and achieve their goals safely. Group Leaders/Managers ensure that appropriate tools, equipment, materials and qualified personnel will be available to complete assigned tasks safely.

Further, they ensure that resources are available for proper maintenance and calibration (if appropriate) of equipment and tools. Both line management and the individuals assigned the work ensure that there is a clear understanding of the work to be completed and that those individuals performing the work are trained and capable of completing the task.

Personnel that are assigned work ensure that the equipment and tools they use are appropriate for the task and are in good working condition. Any discrepancy between needs and availability of either capabilities or condition of equipment/tools is brought to the attention of their immediate supervisor.

5.2.1 Control of Items

Items are controlled and maintained to ensure they are available to those who need them. Items typically controlled at APS include facility equipment, tools, computers and software, chemicals, precious metals, and special materials.

The ALD is responsible for the overall maintenance of the accelerator and associated systems and equipment. Line management makes specific assignments of responsibility for the maintenance and operation of each operationally critical piece of equipment and operational systems. All sensitive equipment, precious materials, chemicals, and special materials also have a custodian. Sensitive equipment is identified with an ANL (CSI) number. Precious materials and special materials are secured and inventoried at least annually.

Individuals are responsible for the security and maintenance of items assigned to them.

5.2.2 Maintenance

Maintenance of equipment that may affect the safety and health of employees or the public or that may result in an insult to the environment is given the highest priority within the APS. Maintenance activities related to the accelerator and front-end components are given the next highest priority and allocation of resources at the APS. Maintenance shutdowns are planned and individual tasks are prioritized based on resources available, importance of the operation, and associated ESH considerations.

Maintenance of equipment and systems not critical to the operation of the accelerator system is planned and completed as resources permit.

5.2.3 Calibration

Calibration of equipment (including measuring and test equipment) is conducted as defined by the manufacturer's recommendations or as required to meet APS visions and goals. The frequency of calibration of each piece of equipment is documented as determined by the responsible group.

5.3 Analyze Hazards and Consequences

Measuring and test equipment is calibrated at predefined time or usage intervals, or whenever the accuracy of the equipment is suspect. The calibration method and interval is based on manufacturer's recommendations, the equipment type, stability, use, required accuracy, and other conditions affecting its capability.

Calibrations are performed against certified equipment having a documented relationship to nationally recognized standards. If no nationally recognized standards exist, the basis for the calibration will be defined and documented. The required accuracy of the test equipment is based on the calibration procedure. Out-of-tolerance conditions found during the calibration process are documented and evaluated by line management for their potential effect on safety or the APS vision and goals. Calibration and the maintenance of associated records is the responsibility of the line organization that controls the equipment.

When requested, APS division QAR assist APS groups with the procurement and scheduling of calibrations performed by on-site or off-site calibration organizations.

5.4 Design/Implement Controls

Once the hazards are known, an analysis is completed to ensure that appropriate controls are in place to minimize potential consequences from the hazards. The analysis may be based on training, experience, and good laboratory practices. Activities with more severe hazard consequences receive a more formal and independent analysis of the controls necessary. Where appropriate, designers and other experts are consulted to ensure that selected controls are appropriate prior to their implementation.

Activities that require complex controls are defined by written instructions (e.g., procedures). The instructions detail the hazards and controls to be implemented.

5.5 Perform Work

Work begins only after appropriate planning has been completed and hazards identified, understood, and controlled. When unexpected issues arise during the performance of the work

that may have significant negative ESH impact on the individuals performing the work, other persons, or the environment, the workers are expected to stop their work. They are to evaluate the effects of the unexpected problem and consult their line manager prior to resuming work. When an individual identifies opportunities for improvement, the worker and his/her line manager will evaluate whether the improvement is significant enough to warrant delaying the work to implement the suggested changes.

5.6 Feedback/Improvement

All employees evaluate the manner in which they perform their own work to assure that they are doing it safely and to the quality standards defined by their supervisors. After a task has been completed, they provide feedback to their line manager or whoever assigned the task performed. Feedback may include simply noting that the activity is complete, completing a form or report, or conducting a functional test to ensure the activity was completed satisfactorily.

Other avenues for evaluating work include assessments (discussed in Sections 9 and 10) and management walkthroughs as described in ANL-E Quality Assurance Procedure 3.4, *Conducting Management Walk-Throughs.* Line managers monitor all work under their purview to ensure that appropriate standards, such as those defined in work plans, are met. APS line management and personnel monitor and evaluate conditions and work practices throughout APS to ensure that activities are conducted safely and are not a threat to the environment or the APS vision and goals. Deficiencies that are able to be corrected immediately are corrected, while those that require funding or more extensive coordination can be documented and tracked using the APS Corrective Action Tracking System (COATS) system.

6.0 DESIGN

Laboratory organizations must: [6]

Design items and processes using sound engineering/scientific principles and appropriate standards.

Incorporate applicable requirements and design bases into the design and any subsequent changes.

Identify and control design interfaces.

For the higher risk activities, verify and validate the adequacy of design products using individuals or groups other than those who performed the work.

Complete any verification activities before approval and implementation of the design.

Complete any validation activities before fully implementing the design product.

6.1 Overview

A disciplined approach to designing a system involves five steps:

First

- A set of functional/design requirements is established.
- The requirements are reviewed and approved prior to proceeding with the design work.
- A set of technical specifications is prepared, if necessary.

Second

- The system is designed per the established requirements and in accordance with appropriate standards, references, and accepted practices.

Third

- The design is verified to ensure that it meets the established requirements and is in compliance with appropriate standards, references, and accepted practices.
- Corrections are fed back to the designer in an iterative process.

Fourth

- The design is approved and the system is created.

[6] The requirements identified within the boxes are those defined in the ANL QAPP, dated September 30, 2004.

Fifth

- The design is controlled as a document in accordance with Section 4 requirements.

Additional guidance for designs activities can be found in the grading matrix found in Appendix A of this document, in the APS Design Review Procedure x.3.1.1, and in the APS Policy on Design, Installation, and Maintenance of Radiation Safety Systems document #1-01304.

6.2 Design Requirements

The requester is the point of contact for every project development initiative. For example, for experimental systems, the requester is the principal investigator (PI) for the project or program. The requester for every project establishes a set of functional/design requirements. The requirements establish targets to be met by the design process that subsequent review/approval personnel can use to ensure that the needs of the requesting organization/individual were satisfied. Functional requirements specifically establish what the system is supposed to do, (i.e., its function and capacity). Design requirements may encompass functional requirements but may also include specific processes and standards to use in the design. For example, a professional engineer shall do the design of a pressure vessel in accordance with the ASME Boiler and Pressure Vessel Code.

Specification and design requirements for systems to be developed by individuals other than the requesters are documented and controlled. Systems that are not complex are less formally documented.

All documented design requirements are reviewed and approved prior to the start of design work. The more complex and hazardous systems are reviewed by at least two independent individuals and approved by the line manager responsible for using the system. Less complex systems may simply be reviewed and approved by the requester. Review suggestions and recommendations are resolved prior to the approval of the design requirements.

6.3 Design

System and facility designs at the APS are developed in accordance with standards and accepted practices appropriate for the complexity, hazard risk, and make-up of the system. While requesters may design some systems, more complex systems require the involvement of a qualified designer or drafter who is familiar with national codes and standards. The requester is responsible for confirming that the level of design formality applied is appropriate for the system.

The designer ensures that the design is internally consistent (e.g., materials are compatible). When appropriate, standardized or previously approved parts, materials, components, and processes are considered. Consideration of ease of use, inspection, maintenance, and repair is a

part of each systems design effort.

Where appropriate, engineering holds are identified for drawings and other appropriate documents, to define the limits beyond which work is not to proceed without review. Action tracking reports are issued for each hold point to describe the reason for and resolution of the hold. These reports become part of the design package and are treated as documents.

6.4 Verification

All designs are reviewed to verify that established design requirements were satisfied. The requester arranges the review and the degree of formality of the review is defined to be consistent with that used to establish and review the design requirements and complete the design.

Formal reviews are conducted by a team comprising at least two technically knowledgeable individuals who are independent (i.e., not directly responsible for the design or operation of the system), the requester's line manager, and the appropriate QAR and ESH Coordinator. The teams are also structured to include all the disciplines necessary to appropriately review the design.

The review includes an assessment of the formality used in the design. In addition, the review team verifies that calculations, computer codes, and analyses used in the design have been documented and reviewed by technically qualified personnel.

The results of formal APS reviews are documented, and the resulting reports either recommend approval of the design or identify issues and offer suggestions, recommendations, and resolution actions. Where the latter occurs, all issues identified in the document are resolved prior to approval of the design. The review committee determines if a second review is necessary.

6.5 Approval

The formality of design approval is based on a risk-based graded approach described in the grading matrix found in Appendix A of this document, in the APS Design Review Procedure x.3.1.1, and in the APS Policy on Design, Installation, and Maintenance of Radiation Safety Systems document #1-01304. The degree of acceptance formality is defined in the system design specifications. For example, a clear, well-defined signature trail is in place for Access Control Interlock System and Personnel Safety Systems design changes, while changes to web pages do not have the same degree of documented formality. The line manager responsible for the design and for the final operation of the system approves the final system design.

6.6 Validation

Once the new system has been constructed in accordance with the approved design, the operation of the system is tested to ensure that it meets the established requirements. If appropriate, a document that defines the test plan (i.e., test cases that envelope the expected limits of the

system) and the test results are issued. All validation documents become part of the design package. Building systems are validated by the occupant and by industrial hygiene and ANL fire protection personnel.

6.7 Documentation of Design

Design requirements, technical specifications, drawings, source code for software, review reports, and other correspondence related to the design of a system are considered controlled documents (see Section 4).

The line manager responsible for the operation of the system is expected to maintain a design package that includes copies of all documents related to the design. The design package comprises the configuration of the system and changes made in accordance with the configuration control guidelines in Section 6.8.

6.8 Changes to Designs

Once a design has been approved, changes to the design, including field changes, are governed by control measures consistent with those used in the original design. The line manager responsible for the design establishes the level of formality required to track future system changes. Simple changes or corrections of obvious mistakes may only require a pen and ink change by the approval authority. These changes are signed and dated to document who made the changes. Significant design changes to more complex systems may warrant justification in writing by the person requesting the change and assurance that analyses and calculations used in the originally approved design are still valid.

Documents related to changes in the original design are controlled and are part of the design package. The line manager responsible for the system ensures that all changes are reflected in the documentation (drawings, system descriptions, etc.).

7.0 PROCUREMENT

Laboratory organizations must: [7]

Establish appropriate requirements for procured items and services, whether from internal or external sources.

Ensure that procured items and services, whether from internal or external sources, perform as specified.

Evaluate prospective suppliers and select a supplier based on specified criteria. As appropriate, this may be done by ANL as an organization or by the requisitioning individual/organization.

Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services. As appropriate, this may be done by ANL as an organization or by the requisitioning individual/organization.

APS procurement activities are conducted in accordance with the policies and procedures in the ANL Procurement Operations Manual and follow the general process given below. Based on the item or service to be procured, there are several possible procurement processes of varying degrees of formality (documentation, approval level, etc.) available at ANL. The APS Procurement Manager determines the appropriate process and formality required for completing a procurement process as specified by the ANL Procurement Operations Manual.

7.1 General Requirements

The procurement process is designed to ensure that 1) the end-user's requirements are accurately, completely, and clearly communicated to the supplier, and 2) the proper product is delivered. A "requisitioner" initiates procurement and determines the detail necessary to clearly communicate the service or product requested. Those items and services whose degree of quality will not cause potentially significant consequences at APS require less documentation than more complex items and services. While the requisitioner makes the initial judgement, all those who sign the requisition or other procurement documents should confirm that an appropriate and consistent level of formality is being applied. See Appendix A for guidance on risk and grading.

The requisitioner supplies the necessary information on the procurement form (purchase requisition, AMOS order, service request, etc.) and is expected to be as specific as possible. For procurement of off-the-shelf items, the requisitioner identifies the part or model number and as complete a description as necessary to allow Procurement to place the order. For all procurements, the requisitioner will include drawings, sketches, or other documentation as

[7] The requirements identified within the boxes are those defined in the ANL QAPP, dated September 30, 2004.

appropriate. If drawings or other design documents are referenced or attached, the requisitioner ensures that the documents meet the requirements of Section 4.

The requisitioner may suggest a vendor and, where possible, several vendors. The requisitioner and all those approving the requisition and procurement documentation must be satisfied that the proposed vendors could provide the item/service and meet any specified requirements. The choice of a vendor is based on a combination of past experience and personal knowledge. When deemed necessary, the requisitioner will arrange for a formal audit or other on-site assessment of the vendor(s) prior to award. The APS QARs can provide assistance in assessing and identifying appropriate vendors. Procurement personnel should also be used as a resource to recommend a vendor.

The requisitioner may specify requirements (acceptance and performance criteria) on the requisition, service request, or other procurement documents. If no requirements are specified, it is understood that the manufacturer's/vendor's/service provider's specifications and processes are sufficient.

Requisitions and service requests are approved at the required level for the amount of money to be spent (i.e., each level of management has approval authority for a certain, defined level of spending).

Division budget personnel review requisitions and service requests to ensure that the appropriate cost code is applied to the procurement. Requisitions and service requests are also reviewed by a QAR when the procurement specifies quality or performance requirements or whenever fabrication is required. The QAR ensures that the appropriate standards are applied and that the documentation is complete and consistent with this QAP.

Requisitions for equipment and materials that have the potential for introducing hazards to the APS are reviewed by the appropriate division's ESH Coordinator to ensure that the necessary controls are in place. Purchases of items such as chemicals, radioactive substances, rotating machinery, hoisting and rigging equipment, personal protective equipment or other safety equipment, furniture, and engineered radiation exposure controls are also reviewed by a Division ESH Coordinator. Further, service requests for facility modifications requiring a Life Safety Code compliance evaluation are reviewed by the appropriate division's ESH Coordinator.

Requisitions for equipment and materials that have the potential for introducing suspect or counterfeit part into the APS environment are reviewed by the appropriate division's Quality Assurance Representative to ensure that the necessary controls are in place.

Suspect or counterfeit items may be found in procured items, installed items found during Laboratory inspections of facilities and equipment, or items brought on site by outside contractors. The range of items found at the Laboratory, other DOE laboratories, and industry that should be considered as possible S/CIs includes the following:

- High-strength fasteners (bolts, screws, nuts, and washers) and load-bearing structural members (I-beams, girders).
- Electrical/electronic components: circuit breakers, current and potential transformers, fuses, resistors, switch gear, overload and protective relays, motor generator sets, DC power supplies, AC inverters, transmitters, computer components, semiconductors.
- Piping components: piping, plates, fittings, flanges, valves and valve replacement products, couplings, plugs, spacers, nozzles, pipe supports.
- Preformed metal structures, elastomers (O-rings, seals), spare/replacement kits from suppliers other than original equipment manufacturers, weld-filler material, diesel generator speed governors, and pumps

The ANL Procurement Department is the main point of contact with vendors. Requisitioners may serve as the resource for technical questions at the discretion of Procurement. The Procurement Department is informed of requests made by a vendor for approvals or judgements on compliance issues.

7.2 Procurement Control

Certain higher-risk procurements require a significant level of quality assurance formality (documentation, technical specifications, etc.). The elements in this section are considered for more complex procurements and may be applied to any procurement as determined by the ANL Procurement Department.

A procurement package is prepared for more complex procurements and includes a requisition or service request with appropriate attachments to convey requirements and specifications. Statements of work, technical specifications, and design documents and drawings define requirements, acceptance criteria, and delivery of an item or service to APS. Technical specifications and statements of work are prepared using the format and content described in the *ANL Guide for Preparation of Statements of Work, Technical Specifications, and Contractual Data Requirements, November 1, 1976*. Statements of work and technical specifications are controlled in accordance with the requirements of Section 4.

Additional requirements may be stated on *Quality Assurance Procurement Requirements (ANL form ANL-407)* or *Acceptance Criteria Listing (form ANL-266)* to list receipt inspection requirements. If used, the QAR and the line manager responsible for the procurement review these forms. If appropriate, the procurement package specifies the need for supplier QA programs, access for inspection, or requirements for inspection records or materials specifications. The requisitioner is responsible for arranging inspections and ensuring that the requirements of the procurement package have been satisfied.

Supplier issues encountered during procurement are processed in accordance with ANL-E Quality Assurance Procedure 2.1, *Nonconformance Process* and the Procurement Operations Manual using standard ANL forms such as the *ANL-267 Report of Nonconformance, and the ANL-311 Supplier Disposition Request*.

8.0 INSPECTION AND TESTING

Laboratory organizations must: [8]

Specify items, services, and processes to be inspected and tested.

Conduct required inspection and testing using established acceptance and performance criteria.

Calibrate and maintain equipment used for inspection and testing.

Inspection at the APS is the process of ensuring that items or services meet specified qualitative and quantitative criteria. **Testing** is the process of actively evaluating items or services against a documented test plan. All items and services received at the APS are reviewed in accordance with requirements specified in procurement documentation and QAP requirements. The requisitioner, who is expected to base his requirements on a consistent methodology, determines the level of review, based on the graded approach defined in Appendix A.

8.1 Requirements

To ensure that the item or service satisfies the criteria specified in the procurement documentation, the requisitioner reviews items and services received at the APS. For certain procurements, the review may simply be either a count by the receiver, or a quick functional check by the requisitioner, while other procurements may invoke a documented test plan with qualified inspectors.

The requisitioner defines the appropriate level of review in the procurement documentation (see Section 7). If no inspection or testing requirements are specified in the procurement package, it is understood that the review will be informal (although it may also be documented) and may consist of no more that a visual confirmation that the item or service received was correct, and whether an item appears to be counterfeit. Suspect/counterfeit items are reported to the appropriate Division QAR and processed in accordance with ANL-E Procedure 2.2 Suspect Counterfeit Items.

Formal inspection and testing is conducted in accordance with defined procedures, test plans, and standard practices by qualified people not directly responsible for the item or service. Formal inspection and testing results are documented as a report, approved by the requisitioner, and reviewed by the division QAR. Formal inspection and testing is conducted using equipment, which has been calibrated in accordance with section 5.2.3 of this plan.

Nonconformances found by the inspection process for quality level A & B procurements are reported to the division QAR via telephone, memoranda, ANL-267 *Report of Nonconformance*

[8] The requirements identified within the boxes are those defined in the ANL QAPP, dated September 30, 2004.

form, e-mails, or travelers. Nonconformances are processed in accordance with ANL-E Procedure 2.1 Nonconformance Process and the Procurement Operations Manual using ANL form *ANL-267 Report of Nonconformance,* or equivalent forms.

When required by the procurement documentation, nonconformances found by vendors prior to shipment are documented and processed in accordance with ANL-311 *Supplier Disposition Request form.*

Nonconforming items are rejected, reworked, returned to vendors, or otherwise controlled by segregation or tagging to prevent inadvertent use. The APS requisitioner performs nonconformance disposition and cause identification, and notifies his/her division QAR of the nonconformance situation.

The division QAR reviews nonconformance disposition and documentation, and determines the root cause and the Price-Anderson Amendments Act (PAAA) applicability. The QAR notifies the APS Price-Anderson Coordinator of any nonconformance having a potential for PAAA reporting. If common causes or other trending indicates an issue to be corrected, such an issue will be handled in accordance with the requirements of Section 3 of this plan.

SECTION C - ASSESSMENT

9.0 MANAGEMENT ASSESSMENT

Laboratory organizations must: [9]

Assess, either formally or informally, their management processes.

Identify and appropriately disposition issues that hinder organizations from achieving their objectives.

Line managers at the APS regularly evaluate the areas under their direction. The objective of their evaluations is to identify where good and noteworthy practices are taking place, and where work is not being performed as expected within regulatory requirements or consistent with the APS vision and goals.

9.1 Requirements

Assessments are performed on both administrative and programmatic efforts and facility conditions in accordance with ANL-E Quality Assurance Procedure 3.1, *Management Assessment,* in order to ensure adherence to ANL policies, to measure and report progress towards meeting performance objectives, and to identify and correct problems that hinder the organization from achieving its objectives. The following are methods used by line management to evaluate the APS:

- Annual ANL Management Assessment
- Surveillance of performance indicators and goals
- Self-assessments
- Operations Directorate
- XOR Management Team
- Intra-APS reviews of experiment proposals and results for publication
- APS Safety Committee reviews of facility conditions and operations
- Root cause analyses and corrective actions based on observations and findings from management and independent assessments
- Walk-throughs of APS work areas

[9] The requirements identified within the boxes are those defined in the ANL QAPP, dated September 30, 2004.

- The Safety Management Records Tool (SMART) program
- Informal assessment of the work in process
- Group meetings
- Periodic review of project documents
- Monitoring the status of COATS items
- Monitoring the status of group task lists

When combined, these efforts give line management a picture of the management processes and whether or not APS goals are being achieved satisfactorily. Written results of assessments are maintained as records in accordance with the requirements in Section 4. Issues identified during assessments are resolved in a timely manner. Methods used to track and resolve issues are identified in Section 3. Conditions adverse to safety, quality, or machine performance are investigated and reviewed to determine the root cause of the condition.

10.0 INDEPENDENT ASSESSMENTS

Laboratory organizations must: [10]

Ensure that independent assessment that measure the quality of items and services and the adequacy of work performance, and that promote improvement, are planned and conducted.

Use assessors that have sufficient authority and freedom from the organization (e.g., an individual division, a facility, or other work unit) being assessed to carry out their responsibilities.

Use assessors that are technically qualified and knowledgeable in the areas assessed.

Independent assessments are established and conducted in accordance with ANL-E Quality Assurance Procedure 3.2, *Independent Assessment* to evaluate item and service quality, to measure the adequacy of work performance or system designs, to ensure compliance with ANL, DOE policies and contract requirements, and to provide an external prospective in order to promote continuous improvement. Once established, the independent assessment group is given authority and freedom to carry out its responsibilities. Persons conducting independent assessments are selected based on their technical qualifications and knowledge in the areas assessed.

10.1 Policy

APS management institutes independent assessments to assist in identifying opportunities for improvement. The ALD ESH/QA Program Manager maintains an assessment plan including independent assessments to evaluate the ESH and QA programs at the APS over a span of three years. The purpose of these assessments is to evaluate the adequacy and the effectiveness of current programs free of direct management bias. The APS Scientific Advisory Committee conducts assessments of programmatic activities to evaluate the effectiveness of the scientific output of the APS. Similar assessments are also coordinated at the division or group level, depending on the needs and desires of line management.

10.2 Assessor Qualifications

Assessors are selected based on their technical qualifications and knowledge of the areas to be assessed. To ensure useful, fair, and credible results, assessors are independent of the line organization requesting and coordinating the assessment.

[10] The requirements identified within the boxes are those defined in the ANL QAPP, dated September 30, 2004.

10.3 Types of Independent Assessments

Representatives from DOE, ANL, and other organizations independent of the APS periodically assess APS operations and activities. The Accelerator Safety Review Committee is an example of a standing committee commissioned by the ANL Laboratory Director to conduct such independent assessments. Programmatic activities at the APS are reviewed by the University of Chicago of the APS scientific and technical accomplishments on a biennial basis.

10.4 Assessment Results

Results from independent assessments are transmitted to the requester and the appropriate APS management. APS management formally responds to all findings and suggestions made by independent assessment teams and takes corrective actions, as appropriate. Actions taken to resolve findings are documented and maintained by the ALD ESH/QA Program Manager, or the committee chair as appropriate.

A summary of ESH and QA assessment results are transmitted to ANL's Office of ESH/QA Oversight.

APPENDIX A – THE APS GRADING MATRIX

The following tables and figure are to be used as a guide in determining the level of compliance for an activity when using the QA criteria discussed in this QAPP. The line manager responsible for the activity assigns the risk level. The risk level is based on the **potential consequence in the absence of any controls** (i.e., the worst case), from Table A-1, and the probability of occurrence, from Table A-2. Figure A-1 gives a general matrix that can be used in conjunction with Tables A-1 and A-2 to group activities into risk levels based on the combination of consequences and probability.

Table A-1: QA Consequence Levels

	Consequence Level (Worst Case)		
	High Consequence	**Moderate Consequence**	**Low Consequence**
Radiation Exposure	≥ 25 rem whole-body	≥ 1 rem and < 25 rem	< 1 rem
Other Impact on Safety and Health	Life threatening to a member of the public or a worker at the APS	Serious injury to a member of the public or a worker at the APS	Minimal impact on the health and safety of the public or a worker at the APS
Environmental Impact	Off-site environmental or radioactive material releases	On-site environmental or radioactive material releases	Negligible impact on the environment
Component Classification	*APS Critical Component* or other safety class structure, system, component, or software identified in facility safety documentation such as the *APS SAD or Conduct of Operations* that is necessary to keep visitor and worker radiation exposure levels below the limits specified by safety analysis System, component, or software identified as high consequence by *the APS Policy on Design, Installation, and Maintenance of Radiation Systems* *Other* structure, system, component, or software specifically identified as high consequence by APS management.	Safety significant structure, system, component, or software not defined as high consequence, but whose preventative or mitigative function is a major contributor to defense in depth (i.e., prevention of uncontrolled material releases) and/or worker safety as determined from hazards analysis System, component, or software identified as moderate consequence by *the APS Policy on Design, Installation, and Maintenance of Radiation Systems* Other structure, system, component, or software specifically identified as moderate consequence by APS management	Structure, system, component, or software that is not critical to the APS vision and goals or division mission, and whose failure would not result in significant risk to worker safety System, component, or software identified as low consequence by *the APS Policy on Design, Installation, and Maintenance of Radiation Systems* Other structure, system, component, or software specifically identified as low consequence by APS management Off the shelf, commercial grade items and services
Cost	Financial loss of greater than $500,000	Financial loss of greater than $50,000	Negligible financial loss
Mission Impact	Significant impact on APS mission or credibility, such as unplanned down time exceeding one week	Moderate impact on APS mission, such as unplanned down time exceeding 24 h	Negligible impact on an individual, a program, or the mission

Table A-2: QA Probability Levels			
	High Probability	**Moderate Probability**	**Low Probability**
Probability	≥ 10%	≥ 0.1% and < 10%	< 0.1%
Complexity	Complex interlocks and controls, multiple functions, multiple energy sources such as electrical, pneumatic, vacuum, and water	Single purpose function, possibly several energy sources, several interlocks and controls	Single function, static installation
Qualitative Description	Likely to Occur	Neither likely or unlikely to occur	Unlikely to occur

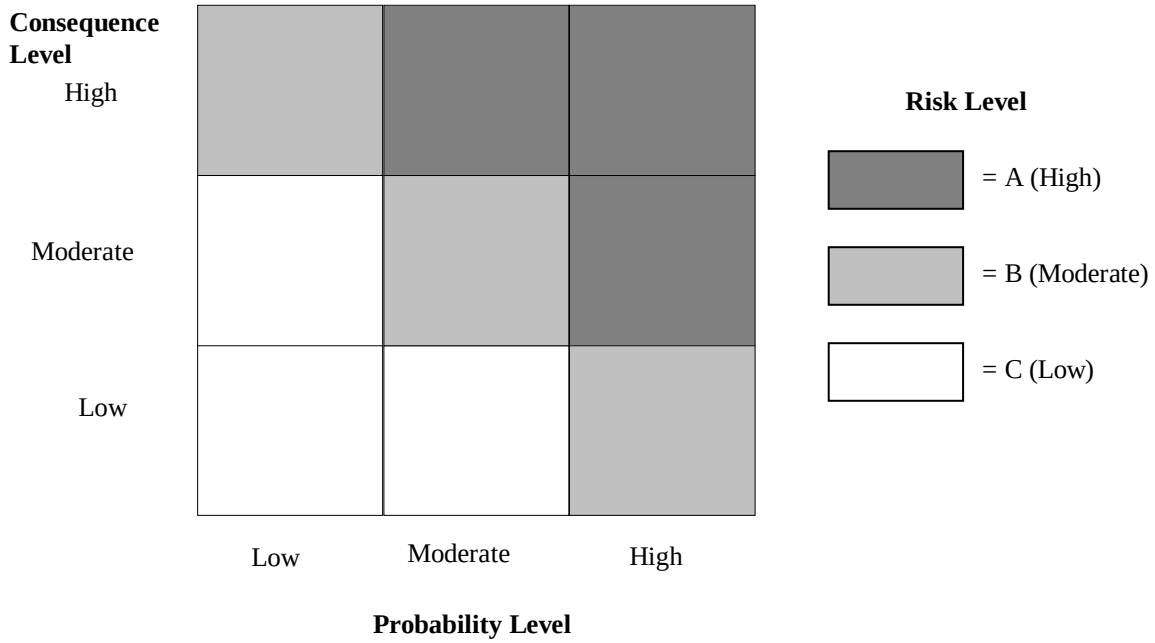

Figure A-1: Risk Determination Matrix from ANL Quality Assurance Manual (adapted from DOE-STD-3009-94, Figure 3.3)

The rows and columns in Figure A-1 are independent. For example, suppose the probability of failure of a given PSS component is low, but the consequence of a failure is high (i.e., serious). According to the matrix, such a failure presents a moderate risk to the APS mission. There are also situations where the apparent consequences of an activity are low or moderate, but compounding factors may result in a serious consequence. Routine clerical and office activities are considered to present low probability of injury and low consequence. Line managers must apply their discretion when evaluating risk categories. Division ES&H Coordinators and QA Representatives are available to assist in establishing a consistent determination between managers.

Based on the QA risk level determined from Figure A-1, Table A-3 should be used to determine the appropriate formality in applying the QA criteria. A Level C activity should have some level of QA; however, it may not be as formal as that for a Level B activity.

Table A-3: Quality Assurance Formality to be applied in accordance with the risk.

Level A – High Risk	**Level B – Moderate Risk**	**Level C – Low Risk**	
Instructions/Training			**Applicable policies, procedures, and forms**
Formal procedures and training, qualification and/or certification is required.	Procedures may be semiformal (memos, operator aids, manufacturer's instructions). Suitable and appropriate training should be given.	Procedures may be informal or verbal. Other than basic orientation training, no other training is required.	APS QAPP Section 2.0 ANL Job Hazard Questionnaire APS New Employee Orientation Checklist
Documents/Records			**Applicable policies, procedures, and forms**
Formal controls and procedures are required for change, access restrictions, protected storage, and final disposition.	Follow APS policy and process for preparation, review, approval, distribution, use and revision.	May require no documents or records.	APS QAPP Section 4.0 Integrated Content Management System (ICMS) APS Document Control Procedures APS DCC Document Change Note Division and Group-specific requirements
Work Processes			**Applicable policies, procedures, and forms**
Formal controls (e.g., assignments, plans, safety analyses, etc.), schedules and milestones, verification and validation, and readiness reviews. See Tables 2 and 3 of APS Policy on Design Installation, and Operation of Radiation Safety Systems	Semiformal controls (e.g., work plans and written memoranda of understanding) qualified personnel, progress reporting required. See Tables 2 and 3 of APS Policy on Design Installation, and Operation of Radiation Safety Systems	Controls appropriate for routine laboratory or office activities. Reliance on professional judgement, good business or lab practices, verbal direction and feedback, and supervisory oversight. See Tables 2 and 3 of APS Policy on Design Installation, and Operation of Radiation Safety Systems	APS QAPP Section 5.0 APS Work Request System APS Safety Assessment Document APS Conduct of Operations Document APS Policy on Design Installation, and Maintenance of Radiation Safety Systems Division and Group-specific procedures
Design			**Applicable policies, procedures, and forms**
Design reviewed in accordance with the APS Design Review Procedure on the APS Policies and Procedures page of the APS Intranet or Independent design and safety reviews, professional drawings, documented functional requirements. Division Director approval.	Design reviewed in accordance with the APS Design Review Procedure on the APS Policies and Procedures page of the APS Intranet or Informal design and safety reviews, detailed sketches, group leader approval.	Design reviewed in accordance with the APS Design Review Procedure on the APS Policies and Procedures page of the APS Intranet or Verbal instructions, informal review by worker, approval by worker if allowed by responsible Group Leader.	APS QAPP Section 6.0 APS Safety Assessment Document APS Design Review Procedure APS Policy on Design Installation, and Maintenance of Radiation Safety Systems APS QAPP Appendix C & D Software Quality Assurance

Procurement/Item Control/Inspection/Testing			**Applicable policies, procedures, and forms**
Technical specifications prepared by cognizant worker, reviewed by requester and an independent cognizant party, general inspection by requester and appropriate QAR, formal receipt inspection by ANL Inspection Department or other appropriate inspection, verification and validation, or readiness reviews. Incoming items inspected against ANL Suspect/Counterfeit Items List	Technical specifications (may include manufacturer's specifications) reviewed by requester, general inspection by requester and appropriate QAR. Incoming items inspected against ANL Suspect/Counterfeit Items List	Items are off-the-shelf or manufacturer's specifications are sufficient. Functional inspection by requester upon receipt. Incoming items inspected against ANL Suspect/Counterfeit Items List	APS QAPP Sections 7.0 & 8.0 P.A.R.I.S ANL-407 Quality Assurance Procurement Requirements form. P.A.R.I.S ANL-266 Acceptance Criteria Listing form. ANL-311 Supplier Disposition Request form. ANL-AEP 2.1 Nonconformance Process ANL-AEP 2.2 Suspect Counterfeit Items
Assessments and Responses to Concerns/Observations/Findings			**Applicable policies, procedures, and forms**
Stop work; immediate attention and corrective action required before resuming work.	Corrective action plan required within 60 days.	Corrective action will be taken, resources permitting.	APS QAPP Sections 9.0 & 10.0 APS ALD ESH/QA Assessment Schedule ANL-AEP 1.2 Corrective Action Tracking ANL-AEP 3.1 Management Assessment ANL-AEP 3.2 Independent Assessments ANL AEP 3.3 Incident Investigations ANL-AEP 3.4 Conducting Management Walkthroughs

APPENDIX B – AUTHORITIES AND RESPONSIBILITIES

ALD ESH/QA Program Manager - The ALD ESH/QA Program Manager reports to the ALD APS. He is the principal point of contact and coordination for both ESH (including NEPA) and QA issues at the APS. He is responsible for ensuring that this Plan is applied in a consistent manner across the APS. Specific responsibilities include:
General

- Preparing and maintaining the APS QAP, and assisting in its implementation;
- Assessing the implementation of quality assurance at the APS;
- Participating in independent assessments;
- Assisting in the resolution of issues;
- Reviewing/revising the APS QAP annually;
- Overseeing the division QARs and ensuring that a consistent approach is being used across each division and the APS;
- Participating in management assessments of the overall APS QA program, and verifying completion of corrective action; and
- Participating in the processing of Occurrence Reports.

Division Directors - Division Directors are responsible for establishing and maintaining the organizational structure, functional responsibilities, and levels of authority necessary to support the division goals and objectives. Further, Division Directors establish appropriate performance measures by which to assess work. Specific responsibilities include:
General

- Ensuring that the requirements of this QAP are implemented at the division level and the appropriate documentation to support compliance is generated and maintained;
- Planning for the division's work, including the establishment of justified budgets, cost estimates and schedules, and the acquisition of appropriate resources;
- Selecting qualified personnel to achieve the mission, goals, and objectives of the division;
- Assessing division performance against stated goals and objectives and taking appropriate action to maintain and improve quality;
- Establishing meaningful objectives and performance indicators and reviewing them periodically for continuing adequacy;
- Implementing processes that promote continuous quality improvement;
- Establishing priorities for resource commitments; and
- Assuring that issues are reported and corrective actions are adequate and timely.

Training and Qualification

- Training and qualification of division personnel, including development, and improvement of their capabilities;
- Reviewing minimum qualifications for safe work practices;
- Establishing appropriate training for areas under their purview;
- Appointing a Training Management System (TMS) representative to administratively handle training records and coordination with ANL's TMS Group;
- Maintaining a tracking system to monitor compliance with training requirements;
- Informing ESH Division of division-specific training requirements; and
- Assessing the training program and incorporating lessons learned into the program.

Quality Improvement

- Establishing an environment that fosters continuous improvement;
- Maintaining interfaces between the technical groups within the division, and among the APS divisions;
- Developing operating plans to support APS operations and maintenance;
- Assessing programs for personal protection, machine protection, safety oversight, and facilities inspection;
- Establishing appropriate work processes; and
- Initiating design and safety reviews of significant changes to overall APS systems under their direction.

Documents and Records

- Maintaining the following records, if applicable:
  - — Experimental proposals
  - — Interim experimental reports
  - — Publications record and file
  - — Division progress reports
  - — Financial status
  - — APS operational statistics

Associate Division Directors –ADDs report to their respective Division Directors on the status of their groups and inform their technical groups of division policy and goals. In the absence of the Division Director, an ADD will be appointed to act on behalf of the Division Director and

assume the authority and responsibilities of the Division Director. Specific responsibilities include:
General

- Supporting the implementation of this QA Plan at the Group Level;
- Developing project plans, engineering designs, and work assignments to support division objectives;
- Communicating division priorities to their technical groups;
- Assisting in developing budgets and schedules to accomplish work assignments in their technical groups;
- Assisting in identifying risks to personnel, equipment, and environment and in developing engineering and administrative controls to mitigate risks;
- Developing key performance indicators that measure progress and improvements for operations within their technical groups; and
- Approving and tracking group task priorities.

Group Leaders/Managers - The Group Leaders/Managers manage and operate their respective operations within the constraints of their individual budget and schedule requirements. Specific responsibilities include:
General

- Implementing the applicable requirements and practices of this Plan and related quality documents in their operations;
- Conducting work in their respective areas in accordance with the prescribed expectations of this QA Plan and in keeping with the principles of continuous quality improvement;
- Defining the key performance indicators that reflect the operation's ability to achieve quality in their processes and work products;
- Communicating the appropriate level of quality assurance (inspection, verification, documentation, etc.) to the employees assigned to them; and
- Proposing, disseminating, and directing effort toward group priorities.

Training and Qualification

- Maintaining compliance with ANL and division training requirements and job qualifications;

- Establishing a training coordinator, or point of contact, to work with the division TMS Representative and ensure compliance with training requirements;
- Reviewing job assignments within the group annually to identify hazards, qualifications, and training required for job assignments;
- Ensuring that personnel have the necessary knowledge, skill, and ability to perform an assignment; and
- Developing task-specific training necessary for personnel to complete job assignments.

Quality Improvement

- Comparing group performance to reliability budget;
- Coordinating schedules with other groups at APS in support of maintenance periods;
- Analyzing issues and implementing/recommending resolutions;
- Monitoring modifications to identify success, failure, and ways to improve reliability or operation;
- Maintaining an appropriate supply of resources to ensure efficient recovery from component or system failures;
- Assessing the systems under their direction to ensure the system is being appropriately maintained;
- Reviewing system design requirements and design; and
- Appropriately documenting analyses in support of design.

Documents and Records

- Maintaining the following records, if applicable:
  - Operating log books
  - Equipment parameter sheets
  - Radiation safety system interlock checkouts
  - Accelerator tunnel entry records
  - Accelerator radiation distribution maps
  - Accelerator status reports
  - Equipment reliability comparisons
  - Accelerator downtime studies
  - Worker qualifications forms
  - Operating safety requirements test data
  - Experiment logbooks
  - Personnel protection interlock validations

Quality Assurance Representatives – The QARs ensure that this QAP is applied in a consistent manner within their divisions and across the APS. Specific responsibilities include:
General

- Assisting in the implementation of this QAP;
- Reviewing the APS QAP annually and providing input for revision, as appropriate;
- Assisting Group Leaders/Managers in evaluating assignments and developing task-specific QA plans, and reviewing, before issue, any task-specific QA plans, implementing procedures and their revisions;
- Assessing implementation of QAP in the division and identifying issues;
- Serving as a conduit to division and APS management for a process of continual quality improvement;
- Participating in independent assessments, and serving as a point of contact for all quality related matters;
- Participating in management assessments of the APS QA program at the division level, and verifying completion of corrective action;
- Informing division management and the ALD ESH/QA Program Manager of the state of the quality assurance program, and bringing issues to the appropriate management level for timely resolution;
- Participating in the processing of occurrence reports, inspection and disposition reports, supplier disposition requests and nonconformance reports;
- Ensuring that appropriate division personnel are given appropriate QA orientation/training and retraining;
- Reviewing requisitions, specifications, acceptance criteria listings and statements of work for procurements and services in accordance with the QAP, and assisting in inspection planning;
- Assessing suppliers in accordance with the QAP;
- Participating in the ANL-E QAR meetings;
- Coordinating the mass calibration of equipment; and
- Ensuring that groups monitor the calibration requirements of equipment.

Quality Improvement

- Assisting in development of plans for upgrades to technical systems fabrication, installation, and operation; and
- Developing corrective action plans for identified issues.

ESH Coordinator – The ESH Coordinators implement and coordinate ESH-related policies at the division level and ensure that such policies are applied consistently within their Division and across APS. Specific responsibilities include:
General

- Ensuring the requirements of this QAP are applied to ESH policies and issues;
- Reviewing the requirements of this plan to ensure that they are not inconsistent with the APS policy that employees work safely;
- Maintaining knowledge of the regulatory requirements pertaining to safety and ensuring that the division and APS are in compliance;
- Assisting Group Leaders/Managers in evaluating work assignments and to develop appropriate job safety analyses;
- Serving as a conduit to division and APS management for a process of continual safety improvement;
- Participating in both management and independent assessments, as appropriate; and
- Ensuring that the training implied by this Plan is completed by APS personnel in a timely manner such that personnel can perform work assignments safely and without harm to personnel, equipment, or the environment.

Personnel - Employees conduct daily activities in accordance with the principles and requirements of this QAP. Each individual is responsible for the quality of his/her work and for being attentive to the principles of continuous quality improvement. Specific responsibilities include:
General

- Informing their immediate supervisor of any conditions that are noncompliant with APS policies, procedures, and instructions;
- Reporting all accidents, occurrences, damage to equipment, and unsafe conditions to their immediate supervisor;
- Using only appropriate tools and equipment, and verifying that tools/equipment are in proper, working condition and that calibration, if required, is valid;
- Maintaining knowledge of emergency plans and procedures, alarms, and responses for their work locations;
- Stopping any activity that poses imminent danger to any individual, the APS vision and goals, their Division's mission, or the environment, and notifying management;
- Completing all required training in a timely manner; and
- Performing their work in accordance with the principles of ISM and the requirements of this Plan.

Quality Improvement

- Understanding specifications of components and systems and procedures for installation and operation;
- Performing the work with attention to safety and proper work practices;
- Reporting successful installations, and any deficiencies of design specification or operation; and
- Suggesting improvements related to systems, ESH, or the APS vision and goals.

Documents and Records

- Maintaining the following records as appropriate:
  - Laboratory notebooks
  - Computer software and data acquisition disks or tapes
  - Progress reports
  - Design packages
  - Safety review documents
  - System descriptions
  - Procurement packages
  - Service requests
  - Process procedures
  - Inspection or test plans
  - Nonconformance, corrective action, QA audits and occurrence reports

APPENDIX C

APS SOFTWARE QUALITY ASSURANCE

1.0 Purpose

This section outlines standard practices for software development and maintenance at the APS.

2.0 Background

The APS is a successful, operating facility. Much of the software has a history of many years of reliable service, and is considered well tested. Hence, the existence of old versions of operational software and software configuration data provides a fallback that mitigates the consequences of problems with new software or new versions of existing software.

Without backup capabilities, the consequences of software problems could be severe, in terms of lost data and damage to the reputation of the APS. This section emphasizes the practices required to maintain viable prior versions of the software used for operations. Prior versions of software are available through three mechanisms: version control of software source; version control of executables and libraries; and routine disk backups.

In addition to the software itself, software configuration files are required to operate the facility. Prior versions of these files are available through two mechanisms: version control of the files and routine disk backups.

In this document, we use the phrase “operational software” to refer to any software in categories I, II, and III as defined by the APS Software QA Plan. For category IV software, these practices are not required but are recommended, i.e., for such software, the reader should substitute the word “should” for all instances of “shall.” Refer to Table C-1 for the definition of these categories. Also, a listing of all software applications currently in use at the APS is given in Table C-2 which includes the function of these applications and the type of controls in place. The table also addresses the methods of review and testing and refers to a point of contact for each application.

3.0 Version Control of Source Code

All operational software at APS shall be version-controlled, which permits tracking changes in software and reverting to earlier versions of source code. This shall be done using a proven system, such as CVS or subversion, which is widely used at APS. The following practices shall be followed:

1. No software shall be installed unless the source code has been committed to the version-control system.

2. Software developers shall be trained in the use of the version-control system for recovering prior versions without disrupting future development.

4.0 Version Control of Executables and Libraries

Executables and libraries are derived from source code. Retention of prior versions of these files is thus not strictly necessary. However, having such versions reduces the level of consequence of an error by reducing the time required to restore the software to the previous configuration. Hence, an additional element of our standard practices states that, where possible and useful:

1. No executables or libraries should be installed without making copies of the prior versions.
2. Prior versions should be sequentially numbered for easy retrieval.
3. Prior versions should be kept on-line for at least one year.

5.0 Version Control of Software Configuration Files

Much of the software that runs the APS is configured by data files. These data files tell the software how to perform specific operations. As a result, the data files themselves are as important as the software in maintaining operations. Because of differences among the types of data files, some files may be kept in a standard version control system (e.g., CVS), while others may not be amenable to this. For those configuration files that are amenable to standard version control, the rules of Section 3 apply. For those that are not, the developer is responsible, with group-leader oversight, for choosing an appropriate method of retaining and retrieving prior versions of files. For example, the method of Section 4 may be a workable option.

In some cases, configuration files are themselves software-generated. In such cases, prior versions of the configuration files need not be kept, although it is recommended to do so if storage is available. In either case, the software that creates the configuration files is subject to version control as outlined above (section 3).

6.0 Control of Software Build Tools and Interpreters

All software is built or interpreted using compilers or script interpreters. These are complex software systems in their own right and are subject to change and upgrade. In addition, some software systems require specialized build tools, for example, specialized compilers are required to build code for digital signal processors. In order to maintain the ability to repair and upgrade software, we must maintain the ability to build software. Hence, software build tools and interpreters must be validated and retained.

In order to accomplish this, the APS Computer Support personnel must maintain a list of software build tools and interpreters used for operational software. Prior to upgrade or removal of any such system, group leaders responsible for software development must be notified and given the opportunity to validate the new version or approve removal of a system.

7.0 Use and Testing of Disk Backups

All data on the file server disks at APS is routinely backed up. Incremental backups occur on a daily basis during the work week. Backups are retained for at least 3 months. Because of the potential importance of backups in restoring operations, it is necessary to periodically challenge the backup system in order to verify its operation. This shall be done for all disks:

1. On which operational versions of executables and libraries are stored.
2. On which the version control repository is stored.
3. On which operational versions of software configuration data are stored.
4. On which accelerator history data is stored.

Challenges to the backup system will occur every six months, or when a new disk in one of the above categories is brought into service.

8.0 Testing and Review

In light of the above controls, the testing and review requirements for APS software are relatively relaxed for all but Category I software - software which meets the DOE O 414.1B definition of safety software, or software which may have personnel equipment safety functions.. Category I software requires a formally reviewed, written test plan with documentation of the testing, all of which is specific to the software and is included in Appendix D.

For other categories, the previous version of operational software is always available and hence the consequences of installing defective software are limited. Nevertheless, it is important that software receive appropriate testing in order to prevent unnecessary loss of beam time. The degree of testing will depend on the application and the experience of the developer, and is decided on an individual basis by the responsible group leader. In some cases, an experienced developer may install software that is not fully tested in order to further the goals of the project or a particular experiment, knowing that the new software can be replaced quickly if a problem occurs.

Category II software, which is systems software used to control the accelerator, generally requires more formal testing. For example, some software of this type is subjected to automated regression testing or to standardized test suites. This category of software is generally used under beta-test conditions for an extended period prior to release to operations. Category III and IV software is tested by the developer, but without a predefined testing regime.

9.0 Software Procurement

All APS software procurements are approved by an appointed Control Point. Approvals are accomplished through the creation of approval threads in the PARIS Requisition System.

10.0 Assessment and Revisions

Because the APS backup process is a major component of APS software quality assurance process, the APS SQA Committee chair will receive automatic email status reports of all backup activities. The chairman will review the status reports on an on-going basis as an assessment of the adequacy of the APS backup process.

The APS Software Committee chairman will revise this document as necessary to maintain compliance with ANL or DOE software quality assurance requirements. All changes and revisions must be approved by the APS Software Committee.

TABLE C-1: APS SOFTWARE CATEGORIES

CATEGORY I:	Most stringently controlled software & firmware. Safety Software used for APS A.C.I.S. and P.S.S. systems.
CATEGORY II:	Systems Software used to control the APS accelerator.
CATEGORY III:	Applications software, i.e., custom codes, display screens, sequential programming, database software.
CATEGORY IV:	Ad hoc software, i.e., user-requested software, software used for experiments, used once and purged "Kludge" software.

TABLE C-2: CATEGORIZATION OF SOFTWARE CURRENTLY IN USE AT THE APS

* Established applying the criteria contained in Table A-1 of the APS QAPP but **in the presence of controls**.
** The point of contact is responsible for ensuring the quality assurance controls applied are in accordance with Appendix A of the APS QAPP.

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
BESOCM Firmware	Operation of beam shutoff current monitors	I	B	Formal test procedure, periodic validation	Nightly backups, code in repository	ASD-DIA	R. Keane
Top-up monitor firmware	Operation of top-up current monitor	I	B	Formal test procedure, periodic validation	Nightly backups, code in repository	ASD-DIA	H. Bui
BPLD Firmware	Operation of beam position limits detectors	II	C	Formal test procedure, periodic validation	Nightly backups, code in repository	ASD-DIA	H. Bui
New Generation Monopulse BPM Firmware	Operation of new generation FPGA-based beam position monitors	II	C	Functional testing by developer and end users	Nightly backups, code in repository	AES-CTLS	E. Norum
Tune Measurements System Firmware	Operation of tune measurement systems for the storage ring, booster, and PAR	III	C	Functional testing by developer and end users	Nightly backups, code in repository	AES-CTLS	E. Norum
Bunch Cleaning System Firmware	Operation of PAR bunch cleaning system	II	C	Functional testing by developer and end users	Nightly backups, code in repository	AES-CTLS	E. Norum
P0 Feedback System Firmware	Operation of P0 feedback system	IV	C	Functional testing by developer and end users	Nightly backups, code in repository	AES-CTLS	N. DiMonte

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
Magnetic Measurement Lab Software	Characterization of insertion devices	III	C	Informal testing by developer. Final testing and acceptance by MD group.	Nightly backups, older versions kept on-line.	AES-CTLS	J. Xu
SDDS Toolkit and SDDS EPICS Toolkit	On-demand and background collection, retrieval, processing, and display of accelerator data. Closed-loop and on-demand control of EPICS-controlled equipment.	II	C	Automated regression testing and group leader review of new components.	versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday
AOP Data Retrieval and Analysis Tools	Retrieval, analysis, and display of accelerator data, including diagnosis of accelerator performance problems.	III	C	Functional testing by developer.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday
Controllaw	Graphical interface to sddscontrollaw program. Used to invoke and control software loops used for stabilizing the beam and equipment.	II	C	Tested with simulator prior to release of new version.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	H. Shang
SaveCompareRestore	Graphical user interface that uses burtrb/burtwb for saving, restoring, and comparing accelerator settings. Used to maintain accelerator configurations.	II	C	Functional testing by developer.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday
Elegant	Accelerator simulation code used to prepare data for configuration and steering of the APS accelerators.	III	C	Automated regression testing.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	M. Borland
Storage ring lattice configuration tools	GUIs used to translate data from elegant into a form used by the controls system.	III	C	Functional testing by developer.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	L. Emery

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
PVMonitor	GUI used to implement "watchdog" processes that can, for example, shut off equipment to prevent a trip. Not used for ensuring personnel safety or equipment protection.	III	C	Functional testing by developer.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday
Procedure Execution Manager, including instances for Storage Ring, Booster, PAR, and Linac	GUI used for presentation and execution of accelerator startup, shutdown, switchover, and other operational procedures.	II	C	Tested during accelerator studies time prior to release.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday
Storage ring physics applications	GUIs used to perform physics experiments with the storage ring.	III	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	L. Emery
Storage ring power supply applications	GUIs used to perform diagnosis, analysis, status tracking, and configuration of storage ring power supplies.	II	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	H. Shang
Storage ring orbit steering applications	GUIs used to perform steering of x-ray beamlines, control the orbit, configure orbit correction, display orbit data, and adjust BPM offsets.	II	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	H. Shang
Storage ring beam-position-monitor (BPM) applications	GUIs used to diagnose, configure, validate, and characterize storage ring BPMS.	II	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	H. Shang

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
Power supply applications	GUIs used for checkout of power supplies during startup.	II	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday
Storage ring radio-frequency systems applications	GUIs used to display data for storage ring RF systems, and used for control functions during physics studies.	III	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	L. Emery
Positron Accumulator Ring (PAR) orbit correction application	A GUI used to correct the orbit in the PAR.	II	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	M. Borland
PAR applications	GUIs used for measurements and analysis of PAR performance.	III	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	M. Borland
Booster applications	GUIs used for measurement and control of booster systems.	II	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	H. Shang
Linac “routine operations” applications	GUIs used for routine operation of the linac, including startup/shutdown, feedback, feedback configuration.	II	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
Linac physics menu	GUIs used for physics measurements on the linac.	III	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	M. Borland
Rf gun applications	GUIs used for conditioning, configuration, and regulation of rf guns.	II	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday
SDDS utilities	GUIs used for display and analysis of data from SDDS files.	III	C	Functional testing by developer.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday
Software development aids	GUIs used to provide information for software developers.	III	C	Functional testing by developer.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	R. Soliday
Insertion Device Controls-EPICS based	Controls all IDs in Storage Ring	II	C	Reviewed by a peer group. Offline testing by developer and system engineer	Nightly backups on multiple servers. Older versions kept online. Software under revision control.	AES-CTL Controls	Marty Smith
Front End Instrumentation-EPICS based	Monitors all Front End equipment in the Storage Ring.	II	C	Offline testing by developer and system engineers	Nightly backups. Older versions kept online. Software under revision control	AES-CTL Controls	Marty Smith
Data Collection and Data Retrieval	Continuously collects data and stores them. WEB interface to retrieve data.	III	C	Informal testing by developer and other system engineers	Nightly backups. Older version kept online.	ASD-AOP Accelerator Operations & Physics	R. Soliday

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
WEB based software	Retrieve data from the APS control system and used by APS Users	IV	C	Informal testing by developer and used by APS Users	Nightly backups. Older versions kept online	ASD-AOP Accelerator Operations & Physics	R. Soliday
Oracle Backup	Backs up Oracle Databases	III	C	Script author tests all development systems	Backups	AES-IS Information Solutions	S. Leatherman
APS Administrative Applications	MIS Applications concerning administrative and business functions	III	C	Small changes tested by developer. New systems reviewed and tested by end-user(s)	Backups, versions kept in separate schemas.	AES-IS Information Solutions	S. Leatherman
APS Operation's Applications	MIS Applications concerning Operations	III	C	The data model is documented in a case tool. Frequent design review meetings and application testing are held on an ongoing basis during development.	Backups, versions are kept in separate schemas.	AES-IS Information Solutions	S. Leatherman
Access Control Interlock System (ACIS)	Control access to accelerator enclosures, (linac, PAR, synchrotron, LEUTL and storage ring), to prevent radiation exposure.	I	B	Formal review procedures for functional requirements, specification, testing, verification and validation (see APS Safety Assessment Document)	Safety software runs on network isolated Programmable Logic Controllers. Internal diagnostics continually monitor controller status as well as the application program's checksum. Application programs are backed up in on-board	AES-SI Safety Interlocks	J. Forrestal

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
					EEPROMs, in the DCC as part of the validation procedure, and stored on APS servers that are backed up nightly. "End to end" annual validation of system hardware and software. System design and configuration subject to applicable sections of the APS Design Review Procedure		
EPICS Base	Basis for all real-time slow controls in APS IOCs.	II	C	Several test suites run at APS and LANL before any new release	Nightly backups, older versions kept online, source code in 2 CVS repositories	AES-CTLS Controls	A. Johnson
Custom EPICS Record, Device and Driver Support	I/O and special processing functions for APS IOCs.	II	C	Informal testing by developer and engineers responsible for IOCs using new version	Nightly backups, older versions kept online, source code in CVS repository	AES-CTLS Controls	N. Arnold
IOC Applications comprising Databases, Sequence programs and MEDM screens	Real-time slow control software for APS IOCs.	III	C	Informal testing by the developer / engineer responsible for IOC subsystem	Nightly backups, for major changes older versions kept online, source code in CVS repository	AES-CTLS Controls	N. Arnold
VxWorks Board Support Packages	Basic operating system for APS IOCs.	II	C	Informal testing by developer and engineers responsible for IOCs using a new version	Nightly backups, older versions kept online, source code in CVS repository.	AES-CTLS Controls	A.N. Johnson

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
EPICS Extensions	Client tools to provide logging, user displays, alarm reporting and acknowledgement etc.	III	C	Informal testing by developers, new features tested by engineers responsible for configuration files	Nightly backups, older versions kept online, source code in CVS repository.	AES-CTLS Controls	J.B. Anderson
Feedback System DSP software	Real-time control software for the Storage Ring Fast Feedback system (Linac, PAR, Booster?).	II	C	Informal testing by developer / engineer responsible for Fast Feedback system	Nightly backups, for major changes older versions kept online, source code in CVS repository	AES-CTLS Controls	F.R. Lenkszus
IOC Database Analysis software	Interface to relational databases containing information about IOC applications and databases, not critical to APS operations.	III	C	Informal testing by developer	Nightly backups	AES-CTLS Controls	D. Quock
Miscellaneous code for control system administration	Tools for control system maintenance, administration, etc.	IV	C	Informal testing by developer	Nightly backups	AES-CTLS Controls	N. Arnold
Solaris systems administration scripts	Customized or in-house systems administration tools	IV	C	Informal testing by developer	Nightly backups	AES-IT Information Technology	K.V. Sidorowicz
Other scripts, tools and application configuration files for centrally-provided software applications		IV	C	Informal testing by developer	Nightly backups, Support Request problem reporting	AES-IT Information Technology	K.V. Sidorowicz
Burt (consists of burtrb and burtwb)	Basic tools for retrieving and restoring accelerator settings.	II	C	Informal testing by developer	Nightly backups, older versions kept on-line, source code in CVS repository.	AES-CTLS Controls	J. B. Anderson

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
Gespac firmware	Real-time control firmware for APS magnet power supplies.	II	C	Informal testing by engineers responsible	Nightly backups, source code in CVS repository	ASD-PS Power Systems	T. Fors
Storage ring real-time feedback applications	GUIs used to configure, control, and utilize the real-time orbit feedback system.	II	C	Functional testing by developer, some during studies time as appropriate.	Nightly backups, older versions kept on-line, source code in CVS repository.	ASD-AOP Accelerator Operations & Physics	L. Emery
Other Power Supply software	Various scripts and software tools	III	C	Informal testing by developer	Nightly backups, source code in CVS repository	ASD-PS Power Systems	J. Wang
Personnel Interlock Safety System (PSS) Application code developed by AES-SI group.	Personnel Access Control protection in the APS Experiment Stations.	I	B	Requirements System Code Verification Validations	Instructions-Formal procedures Documents-Formal CFM, backups Work Processes-Formal plans schedules, testing Design-Formal reviews, functional requirements Inspections-reviews, verifications, validations Assessments-stop work, corrective action	AES-SI Safety Interlocks	A. Boron, V. Nguyen
Personnel Interlock Safety System (PSS) COTS software including real time operating (RTO) systems and other development software.	COTS RTO system for Personnel Access Control protection into the APS Experiment Stations. COTS development software system for Personnel Access Control protection into the APS PARTNER USER Experiment Stations	I	B	Requirements System Code Verification Validations	Instructions-Semiformal procedures Documents-Semiformal CFM, backups Work Process-Formal plans, schedules, testing Design-Semiformal reviews, functional	AES-SI Safety Interlocks	A. Boron, V. Nguyen

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
					requirements Inspections-semiformal verifications validations Assessments corrective action plan -		
Front-End Equipment Protection System (FEEPS) Application code developed by AES-SI group.	Equipment protection in the APS Front-End area of the SR.	II	B	Requirements System Code Verification Validations	Instructions-Semiformal procedures Documents-Semiformal CFM, backups Work Process-Semiformal plans schedules, testing Design-Semiformal reviews, functional requirements Inspections-Semi-formal verifications, validations Assessments-corrective action plan	AES-SI Safety Interlocks	P. McNamara, N. Friedman
Front-End Equipment Protection System (FEEPS) COTS software including real time operating (RTO) systems and other development software.	COTS RTO system for protection of Front-End equipment in the SR. COTS development software for protection of Front-End equipment in the SR.	II	B	Requirements System Code Verification Validations	Instructions-Semiformal procedures Documents-Semiformal CFM, backups Work Process-Semiformal plans, schedules, testing Design-Semiformal reviews, requirements Inspections-semiformal verifications, validations Assessments-corrective action plan	AES-SI Safety Interlocks	P. McNamara, Nick Friedman

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
Liquid Nitrogen Control System Application code developed by PSS.	Software to monitor and control the LNDS.	III	C	Requirements System Code Verification Validations	Instructions-Semiformal procedures Documents-Semiformal CFM, backups Work Process-Semiformal plans, testing Design-Semiformal reviews, requirements Inspections-semiformal verifications, validations Assessments-corrective action plan	AES-ASO Experiment Operations Support	M. Smith
LEUTL End Station Access Interlock System Application code developed by AES-SI group	Personnel Access Control protection from Laser light in the LEUTL End Station.	III	B	Requirements System Code Verification Validations	Instructions-Semiformal procedures Documents-Semiformal CFM, backups Work Process-Semiformal plans, schedules, testing Design-Semiformal reviews, functional requirements	AES-SI Safety Interlocks	J. Hawkins, Mike Fagan
Beam Line Equipment Protection System (BLEPS) Application code developed by AES-SI group.	Equipment protection in some of the APS Experimental Stations.	II	B	Requirements System Code Verification Validations	Instructions-Semiformal procedures Documents-Semiformal CFM, backups Work Process-Semiformal plans, schedules, testing Design-Semiformal reviews, functional requirements Inspections-Semiformal verifications, validations Assessments-corrective action plan	AES-SI Safety Interlocks	J. Hawkins, Nick Friedman

Software Application Name or Type	Function	APS Software Category	APS QA Level*	Type of Testing and Review	Other Controls in Place	Responsible APS Group	Point of Contact Name **
General Office COTS software.		III	C	Requirements System Code Verification Validations	Instructions-Semiformal procedures Documents-Semiformal CFM, backups Work Process informal, testing Design-informal reviews Inspection- informal validations Assessments-corrective action plan	AES-SI Safety Interlocks	J. Hawkins
Experimental software	Test feasibility or implementation of control and data-acquisition software; provide best-effort solution to urgent user requirements	IV	D	Developer's discretion	Nightly backups	AES-BCDA Beamline-Control & Data Acquisition	P. Jemian
Control and data acquisition software	Control beamline devices or acquire and store data from beamline devices.	III	C	Informal testing by developer and users	Nightly backups, older versions kept online in ready-to-run condition. Revision control, source code kept in CVS repository.	AES-BCDA Beamline-Control & Data Acquisition	P. Jemian
B420 RF Waveguide Switching System HMI/Plc	Synchronize the opening and closing of the RF Waveguide Switches and Shutters for the B420 Waveguide switching system.	II	B	Functional tests, independent validations, ACIS validations	ACIS and RF radiation monitoring	ASD-RF RF	G. Trento
B420 RF Test Stand Waveguide Shutter Switching System HMI/Plc	Synchronize the opening and closing of the RF Waveguide Switches and Shutters for the RF Test Stand.	II	B	Functional tests, independent validations, ACIS validations	ACIS and RF radiation monitoring	ASD-RF RF	G. Trento

Appendix D

SOFTWARE DEVELOPMENT PLAN FOR ACIS AND PSS SOFTWARE DEVELOPED BY AES-SAFETY INTERLOCKS GROUP

ADVANCED PHOTON SOURCE AT ARGONNE NATIONAL LABORATORY

REVISION RECORD

Revision	Dated	Comments
0		Initial release

1. INTRODUCTION

1.1 Background

This document is a guide for how software development is to be conducted within the Advanced Photon Source Engineering Support Division (AES) in the Safety Interlocks Group (SIG). Specifically, the plan identifies the engineering methodology used to develop and maintain software used in the PSS and ACIS deployed at APS. APS Category I software is defined in Table 1 of Appendix C of the APS Quality Assurance Program Plan (QAPP) which is found in the APS Integrated Content Management System (ICMS) as document APS_058185. In a safety system, it is required that only the authorized tested version of a system be installed. A SDP provides the mechanism whereby assurances can be made that the appropriate software is being used.

Contained within this plan are software work activities that provide a basis for planning, updating, maintaining and operating safety software in the SIG that are compliant with the APS QAPP, ANL QA Procedures Manual-2.3, and the Safety Software Quality Assurance (SSQA) DOE O 414.

1.2 Scope

This SDP applies to all Safety or Category I software produced for use in PSS and ACIS applications at APS. The SDP begins with determining appropriate requirements and continues for the life of the software.

1.3 Purpose

The purpose of this document is to define both technological and management aspects of the software development process used by the SI Group. Also, this SDP demonstrates the means by which APS, ANL and DOE quality assurance program goals are achieved.

The goal of the SDP is to minimize its impact on the software development process while enhancing the assurance that correct systems are being delivered and maintained. This goal is achieved by encapsulating traditional development activities inside a controlled environment and by using recognized good practices for safety software development. Since the PSS and ACIS safety software applications are implemented in Programmable Logic Controllers (PLC), the IEC 61511 is referenced as a guide in this SDP. The software configuration management (SCM) function is an important part of any SDP so the ANSI/IEEE Std. 1042-1987 is referenced in this SDP as guideline for SCM.

2. THE DEVELOPMENT PROCESS

As with any software development effort, software project management is required. This SDP identifies specific significant software tasks that are used to control/manage the software project. Tracking of these tasks is achieved via the configuration management function of this SDP. This entire SDP is summarized in Figure 1 which includes major types of work activities used in the development of safety software in the SIG.

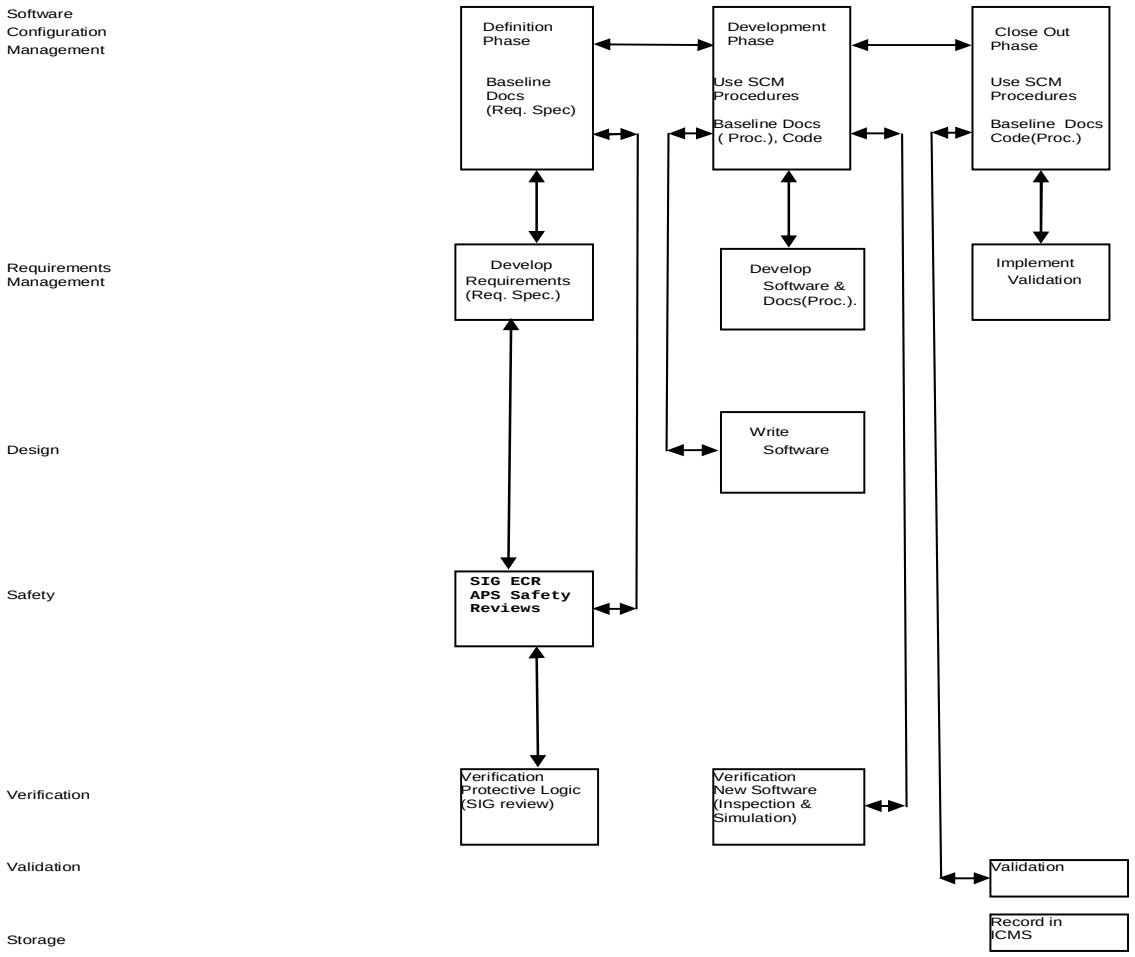

Figure 1. Major types of work activities used in the development of safety software in the SIG.

2.1 Software Development Plan Phases

The three major software phases/tasks, Definition, Development, and Close Out, are shown across the top of Figure 1.

Category I software utilized by the AES-SIG is developed and controlled with stringent review, testing, and security procedures. The following sections describe the procedural steps/phases required for new software development and modifications to existing software.

The development functions proceed in an informal manner while the configuration management system maintains an orderly development and change process. Official promotions from one phase to another are only done after appropriate reviews are completed. Conditions requiring correction of safety related functionality are referred back to the Definition Phase, thus helping to assure that the corrective action is consistent with the systems intended function.

2.1.1 Definition/Requirements Phase

A software project begins with the definition phase. New software or changes to existing software is initiated via the SIG Engineering Change Request (ECR) process. At this phase the central baseline document is the requirements specification which is a simple unambiguous statement of the problem to be solved. It is a document which contains the functions required to be realized. It includes safety functions and how they are linked to various mandated policies. Contained in this document is an accurate and detailed description of the functional operation of the system under design, with types of inputs, outputs, and any timing requirements Also, this document includes the software environment in which the function is needed, and operational scenarios. The content of this requirements specification may be captured in more than one document (i.e. a general requirements specification and one other requirements document that captures the details of operational scenarios).

Any changes to existing/operational software are also initiated in the definition phase. These changes are tracked with the SIG ECR process, which is implemented using ICMS.

The safety implications of the software and system are examined during the definition phase via the SIG ECR process. The SIG ECR process grades the level of safety risk and then initiates the appropriate level of review.

Before detailed design and implementation of any Category I SIG software component begins, a requirements specification is written and approved after appropriate reviews are completed. The approved requirements specifications, referred to as the Requirements Package, are placed under configuration control as a configuration item via ICMS.

Subsequent modifications to the requirements will result in new revisions of the Requirements Package.

2.2 Development Phase

The software generated by the developer in this development phase is based on the promoted/approved requirements specification from the definitions phase. During the development phase the software undergoes informal integration and testing. The SIG category I software is developed using standard programming practices as described in the SIG Programming Style Guide and in the IEC65111 standard. The PLC development environment used for SIG category I software is a limited configuration language, thus the Programming Style Guide functions, in part, as a software design specification.

The protective logic code is available to appropriate reviewers and other parties. Testing is done to verify proper execution of the software by either code inspections or lab simulations.

Software developmental risks of the design approach, which include both physical and functional interfaces, like version compatibility, are identified, evaluated and addressed as a part of the SIG ECR process. The validation procedure is independently reviewed to insure that all system functions and components are adequately and independently tested.

The Development Package which includes software, input/output (I/O) lists, fault lists, memory maps, executed verification tests and validation procedures are reviewed before it is released to the Close Out Phase. The SIG SCM Procedures define in detail the work flow path for SIG Category I software undergoing development or modification.

2.3 Close Out Phase

This step in the software development process is designed to validate that the functionality of the software is complete and correctly implements the requirements specification as captured in the Development Package. . The test is performed and signed off as each function is proven. Test results are reviewed and signed off by the appropriate persons at which time these documents are placed under configuration control.

The initial Close Out Package is essentially the Development Package, which is the complete set of validation procedures and the software elements released from the associated Development Phase

The validation procedure is executed at the target site. Exceptions that may occur during this validation process are reviewed and approved as described in each validation procedure. A completed validation procedure is reviewed for correct execution. This is the first time that the software is officially deployed in the target environment.

Any approved changes are implemented using ICMS work flow. Changes to other baseline elements are made as needed.

3. Software Development Plan Work Activities

SIG Category I or safety software is produced using a controlled process that includes defined software work activities consistent with DOE O 414 and the ANL/APS Safety Software Quality Assurance (SSQA) program. The safety software used in the ACIS and PSS has been evaluated with respect to the DOE G 414. The conclusion of this evaluation is that both ACIS and PSS safety software is configurable Level C safety management software, as indicated in Table 2 of DOE G 414.1-4. Thus according to Table 4 in DOE G 414.1-4 8 of the 10 SQA activities may be implemented using a graded approach. Figure 1 shows many of the SSQA work activities. A complete list of the 10 SSQA activities and how they interact with the SDP are shown below.

3.1 **Software Project Management** (Graded)

Software project management is a key element that efines and guides the SDP to satisfy project requirements. The identification and tracking of all significant software tasks/phases are described in the SDP. As seen in Figure 1 the main tasks are Definition, Development and Close Out. Estimates of the task durations, and resources allocated to tasks are addressed in the Definition phase via SIG ECR process and regular group meetings. IEC 61511 Section 5 is used as a reference to guide this activity.

3.2 **Software Risk Management** (Graded)

Software risk management addresses non-safety related software risks that could stop or hinder successful project completion. Examples of some such risks for safety software applications are:

- Incomplete or volatile software requirements;
- Hardware constraints that limit the design;
- Incomplete and undefined interfaces;
- New versions of the operating system;
- Undefined or inadequate test acceptance criteria;

Such software management risks are identified and mitigated in the Definition Phase. The IEC 61511 standard identifies software development risks and methods for resolution and thus is used to address software management risks. Some software management risks like selection of hardware, firmware and operating systems are identified and resolved during the SIG ECR and APS design review process. IEC 61511 Section 8 is used as guide in this activity.

3.3 **Software Configuration Management** (Graded)

Software Configuration Management (SCM) is the backbone of the software engineering process. A unified process flow is used to support the four strategies of: Tractability Management, Baseline Management, Change Management, and Configuration Identification. IEC 61511 Sections 5 and 12 are used as guides in this activity as is the IEEE Std. 1042-1987. These SCM functions are implemented in the SIG's Software Configuration Management Procedure.

3.3.1 Tractability Management

Development tractability means that it is possible to trace the development process from some enabling document through successive engineering steps to a logical conclusion.

3.3.2 Baseline Management

APS Category I software typically uses sequential baselines which allows for an orderly development process.

3.3.3 Change Management

Change Management procedures allow effective control and track changes in systems under development and deployed in the field. For SIG Safety Software, the software starts with an approved ECR. The configuration management of the safety software is described in the SIG Software Configuration Management Procedure.

Media Control and Security

All documents requiring a signature are placed under configuration control via ICMS. All code and test records are store in either electronic or hard copy format with provisions for disaster recovery. Electronic storage meets the requirements of the ANL Computer Protection Policy, which has provisions for backups.

3.4 **Procurement Management** (Full)

The safety software purchased for ACIS and PSS is commercial off the shelf operating systems and development software for PLC's. Safety software developed with these commercial platforms uses only features that are provided. Thus, quality of this commercial software is accepted based on the large user base. Additionally, the SIG performs some tests on newly procured operating and development software to verify its basic operation. IEC 61511 Section 12 is used to guide this activity.

3.5 **Software Requirements Management** (Full)

The software requirements are identified in the Definition phase of the SDP and include the following elements; safety functions, performance, and interface requirements. Additionally, the software requirements are reviewed for correctness, consistency, and testability as part of the ECR, BSDRSC and RSPPC work flow as described in the Definition phase. IEC 61511 Section 10 and 12 are used to guide this activity.

3.6 **Software Design and Implementation** (Graded)

During the Development phase, the developer uses the requirements package as a basis for designing the software system. Unit and integration testing is performed informally to the satisfaction of the developer. The developer works with the verification activity to perform formal unit and integration verification testing as described in the Development phase of this SDP. The software design description is a combination of a Programming Style Guide and the comments in the source code. IEC 61511 Section 12 is used to guide this activity.

3.7 **Software Safety** (Graded)

The safety activity is mainly accomplished during the Definition phase as described in this SDP. Safety analysis is includes safety reviews by the SIG as part of the ECR process and the APS Safety Review process. The initial ACIS and PSS safety software was developed based on the results of event tree safety analysis. Safety hazards that are relevant to ACIS and PSS software are identified and described in the APS Safety Assessment Document. Subsequent software development reuses existing tested software as a baseline. The strategy of code reuse is a common industry good practice to reduce software failures including those that have safety consequences. IEC 61511 Section 12 is used to guide this activity.

3.8 **Verification & Validation** (Graded)

Verification &Validation occurs in both the Development and Close Out phases of this SDP. Verification activities during the Development phase consist of code reviews and/or simulation of the software on test bed platforms. Software verification is done before the code is released to the target system. Once the software is deployed to the target system a functional validation is performed that includes testing both normally designed safety functions and likely off normal conditions. IEC 61511 Section 12 is used to guide this activity.

3.9 **Problem Reporting and Corrective Action** (Graded)

Problem identification during the software development phases is accomplished via the feedback structure in the configuration management process. The use of ICMS for

document reviews incorporates a work flow that records comments about software problems. During the Definition and Development phases in addition to formal problem reporting via IMCS informal interoffice communications are used describe problems. During the Close Out phase software problems are recorded in the validation procedure and execution of the validation is stopped until the problem is resolved. Once the software is operational then the APS RMD process is used to report and track problems.

3.10 Training of Personnel (Graded)

The qualifications of staff involved in safety software development are listed in their position description. Continued professional training is encouraged by management and results in periodic attendance at PLC classes, safety conferences, safety courses and industry conferences. Periodic evaluation of the training and performance is done by APS management.

4.0 Contractor Assessment

DOE Contractors, like APS, are expected to assess the adequacy and effectiveness of their safety software controls in accordance with DOE O 414.1C and its guide DOE G 414.1-4. A sample method of how to perform self assessments of safety software consistent with DOE O 414.1C and its guide DOE G 414.1-4 is listed in appendix F of the guide. APS management will develop and administer a contractor assessment plan that includes safety software developed by the AES SIG.